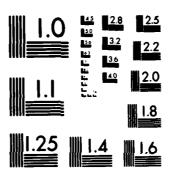
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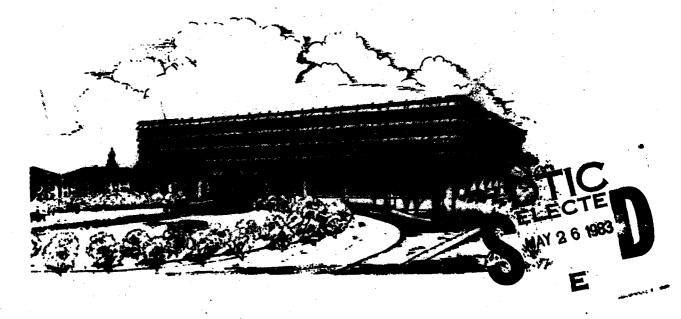
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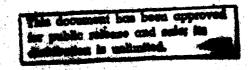
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This report covers the period (1 October 1981 thru 30 September 1982).

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FORWARD

The enclosed annual progress reports constitute documentation of the continuing review of approved research by the WRAMC Institutional Review Board (Clinical Investigation Committee (CIC) and Human Use Committee (HUC)) which is required by federal and local regulations.

Requests for annual progress reports are sent to investigators in August, and the reports are due 15 October. When the annual progress reports are received by Department of Clinical Investigation (DCI), they are checked for accuracy by our DCI editorial staff and sent to an institutional review board member for review. This reviewer may either recommend approval of the annual progress report, request additional information from the investigator, or propose scrutiny of the annual progress report by the entire board. The process of acquiring additional information from investigators is time-consuming but usually results in approval of most annual progress reports, leaving few for review by the entire committee. All annual progress reports in the current report have been approved by this committee process and therefore represent the culmination of the review process for ongoing research.

The progress reports for FY-82 utilize our adaptation of the recommended HSC format. Each investigator is specifically asked whether significant unexpected side effects have occurred during the study, thereby assuring that the CIC and HUC will have an opportunity to assess the risks and safety of human use prior to approving the continuation of the study for another year.

The compilation of this report and the editorial review of over 500 annual reports could not have been accomplished without the perseverance, patience, and proficiency of Mrs. Ethel Ervin.

DEPARTMENT OF CLINICAL INVESTIGATION

FY-82 saw continued growth of the WRAMC Clinical Investigation We added 170 new protocols to the 372 which were ongoing at the year's start. There were more than 145 publications resulting from approved Clinical Investigation projects. The growth in the number of approved protocols reflects the improved health of the Army Medical Department with both the number and quality of personnel essential for clinical research increased efficiency now present in the review process. Under policies now in operation at OTSG and HSC, protocols not involving an investigational drug have potential for having completed the review process within 30 days. "Expedited review" of certain low risk protocols has been in place for two years at WRAMC, potentially permitting approval to be granted within weeks, and the most recent improvement in the protocol review process, was the delegation of approval authority from OTSG to HSC for drug-company sponsored investigational drug protocols, which has resulted in HSC's approval of most drug company sponsored drug protocols within two weeks of receipt. Department of Clinical Investigation (DCI), WRAMC, has been very fortunate to have had and continue to have outstanding personnel facilitating the protocol approval process, Iris Hepburn, and more recently Kanika Brookins and Judi Fisch.

It must be emphasized that this annual progress report not only records the progress during FY-82, but documents the process by which each ongoing protocol is reviewed at least annually, by the WRAMC Clinical Investigation Committee (CIC) and Human Use Committee (HUC), our institutional review board (IRB), as required by DHHS and FDA regulations. This review is necessary to insure the protection of human subjects involved in WRAMC Clinical Investigation projects.

The members of the WRAMC CIC and HUC deserve special recognition for their selfless devotion of time to the review and approval of other's research protocols. Expedited review, counselling sessions with investigators, and more intensive annual review of research projects have created additional demands upon their time. They can be gratified that their efforts have resulted in a quality of institutional review of research at WRAMC which is unsurpassed.

During FY-82 progress was realized in multiple areas. The Animal Research Laboratory, under Fred Coleman, fully supported several research protocols, including kennelling and microsurgery. A cooperative agreement for veterinary support of the laboratory with WRAIR was ratified. The Vietnam Head Injury Study (VHIS) evaluated approximately 200 more subjects, bringing the total to about 300. It was rewarding that the health status of many veterans was improved as a consequence of their participation in the study. CPT Patricia Young's Biochemistry Lab developed state

of the art methodology for apolipoprotein and cholesterol ester measurement. MAJ Ollie S. King's computers were purchased, making automation of protocol and supply data an attainable dream. Despite an ever increasing workload, Mr. Mack Burton continued to keep track of budget and supplies unerringly. Kyle Metaoolic Unit (KMU) continued its tradition of high productivity in Endocrinology, and the programs in Gastroenterology, Pulmonary, Allergy, Oncology, Audiology, and Infectious Disease received national recognition.

During FY-82, DCI supported our Army mission and directives by the Chief of Staff. Several protocols of special military interest were the Carlisle over 40 screen of patients for Coronary Artery Disease, which compared several non-invasive modalities for assessing Coronary Artery Disease, and a study involving behavioral modification techniques directed at improving fitness in the Carlisle War College population. DCI also made arrangements to accommodate the Phase II Drug antimalarial program at WRAMC, which should more optimally protect the involved volunteers and provide an instructive patient population for medical residents and Infectious Disease Fellows. DCI staff members also made individual contributions to readiness. LTC Boehm attended the Red Flag Exercise, CPT Young earned the Expert Field Medical Badge, SFC Moody was a key member in the team that planned and implemented the WRAMC field training exercises. DCI

is delighted to have a new Assistant Chief, MAJ (P) Wayman W. Cheatham, who brings field experience to the assignment, and a biostatistician, Mrs. Judy Evaul. Due to the availability of these personnel and LTC Brian G. Schuster, who is on loan from WRAIR as our other Assistant Chief, DCI can offer outstanding consultative expertise.

The future of DCI at WRAMC holds challenges and excitements. There is currently a trend to entrust the protocol review process to the local institutions, both within the federal government and the Army, and we at WRAMC must continue to meet that challenge. The program has grown to the extent that present resources at WRAMC are no longer sufficient for all our needs and research aspirations. Flexible approaches for procurement of necessary personnel will need to be developed, as well as innovative ways for obtaining sources for funding. At year's end some of the unresolved issues with potential for enhancing support included:

- 1) Feasibility of support from drug companies during participation in drug company sponsored studies.
 - 2) Access to grant funding from other federal agencies.
- 3) Feasibility of obtaining personnel support from outside to assist in collaborative studies.

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UNIT SUMMARY SHEET

1. Mission Changes:

- a. The Vietnam Head Injury Study was fully staffed and implemented: 278 patients were evaluated during FY-82. Support from the 57th Aeromedial Evacuation Squadron, Scott AFB, ILL. and the American Red Cross in the transportation of these patients to and from their homes for the study has been excellent.
- b. Additional laboratory space in the basement of building 7 was obtained to support expanded requirements of the Animal Procedures, Kyle Metabolic, and Organ Transplant laboratories. Two additional "Bio-Clean" containment units were obtained for the Animal Procedures Laboratory which now boards approximately 50 small animals.
- c. The recently completed manpower survey has recognized the increased need for personnel to support WRAMC sponsored research. Much of this was documented from the work done by the investigators during their off-duty hours.

2. Personnel Actions, Current Strength

a. Personnel hired on temporary appointment and term appointment to support WRAMC research projects.

Alston Stephanie	GS O	0699	Temporary
Anderson Jeffrey	GS 09	0644	Temporary
Youm Youngil	GS 12	0858	4 yr Term

b. Personnel hired on a 4 year term appointment and paid by Grant funds from V.S. to support the Vietnam Head Injury Study.

Brown Herbert	GS	11
Fair Christine	GS	11
Parker Yvonne	GS	05
Rohland Anne Marie	GS	06
Rosenberg Jennette	GS	11
Spencer Elmer	GS	80
Spizler Judy	GS	09
Vinkenes Mark	GS	09
Zirk Deborah	GS	09

c. Personnel hired for a 4 year term appointment are paid for by Grant funds from NIH to support the Hematology-Oncology research studies.

Bailey	Carolyn	GS	09
Brooks	Frances	GS	05
Harris	Carolyn	G\$	05

d. Current Manpower

Description	<u>Grade</u>	Mos	Br	Actual	Name
C, Dept of Clin Invest	05	61F9C	мс	1	Boehm

d. Current Manpower, Con't

Description	Grade	Mos	Br	Actual	Name
Asst C, Dept of Clin Invest	04	61F9B	MC	I	Cheatham
Asst C, Dept of Clin Invest	05	61F9B	МС	1	Schuster*
Lab Officer (Admin)	04	68F9D	MSC	1	King
Biochemist	03	68C00	MSC	I	Young
Dietitian	03	3420	AMS	1	Carlson
Med Lab NCO	E7	92B	AMED		Moody
Med Lab SP	E7	928	AMED	1	Hayes
Med Lab SP	E4	92B	AMED	1	MacDonald
Science & Eng	E6	01Н30		1	Shelton
Supv Resch	14	1320	GS	1	Bruton
Chemist					
Microbiologist	12	0403	GS	1	Dobek
Microbiologist	12	0403	GS	1	Ciak
Admin Officer	11	0341	GS	1	Burton
Physiologist	11	0413	GS	1	Lukes
Physiologist					
Bio Lab Tech	09	0404	GS	2	Dickson Butler
Med Tech	09	0644	GS	2 .	Armstrong Burgess
Chemist	11	1320	GS	2	Dawson Rice
Chemist	09	1320	GS	1	Maydonovitch
Med Tech	09	0645	GS	1	Barnes
Bio Lab Tech	09	0404	GS	i	Coleman
Med Tech	07	0644	GS	2	Vacant Br <i>ow</i> n

^{*}Individual is actually assigned to WRAIR

d. Current Manpower, Con't

Description	Grade	Mos	<u>Br</u>	Actual	Name
Secy, Steno	07	0318	GS	1	Ervin
Edit Asst	07	1087	GS	1	Vacant
Supply Tech	06	2005	GS	1	Laster
Clk, DMT	05	0316	GS	1	McAnnally
Edit Asst	06	1087	GS	1	Coleman
Bio Lab Tech	05	0404	GS	1	Martin
Clerk-Typist 3. Investigation P	04 rogram Sum	GS	1	Brookins	
Number of Activ	s	417			
Number of Compl	125				

4. Incentive

The Bailey K. Ashford Award, presented annually to the house staff member at WRAMC whose research project was voted the most outstanding contribution to clinical investigation, was given to David J. Perry, MAJ MC, for his research in the area of head and neck cancer.

5. Funding FY-82

Civilian Personnel	\$ 723,000
Civilian Personnel (Reimbursable Grants)	198,000
Military Personnel	363,831.41
Travel	27,400.00
Contracts	290,000.00
Supplies	645,000.00
MEDCASE	331,396.97
Total	\$ 2578,628.38

DATE: 29 NOV 82 LIGHT NO.		Sivinis	Incapp	Firm. X		
STARTILLS DATE: January 19	80 DATE GE	<u>दिवस्तार होता</u>	November	1982		
Key Noos: Primary thrombocytosis; Hydroxyurea						
Time of Project: PVSG Protocol-12: "Efficacy trial using hydroxyurea (HU)						
in the treatment of primary thrombocytosis."						
Paincipal Investigator(s): Daniel B. Kimball, Jr., COL,MC.						
ASSOCIATE INVESTIGATOR(S): Sta	iff and Fellows of	Hematolo	xgy/Oncology	/ Service		
FACILITY: HRAYE	Dept/Sic: Depa	rtment of	Medicine			
Accumenative PEDCASE Cost:	ROCUMBLATIVE CONTRACT	Cosr: /	CCUMULATIVE S	UPPLY COST:		
FY-83 PECCASE: CONTRACT COST:	: SUPPLY COST:	DATE OF CO	MITTEE APPRO	va. Oe		
		ANNUAL PRO	GRESS REPORT	FEB 8 6 1982		
Study Osuscrive: To study the	usefulness of hy	droxyure	a (HU) as a	non-		
alkylating o	chemotherapeutic a	yent for	the treatme	ent of		
TECHNICAL APPROACH:	·			_		
No change	es were rade in th	e study o	design durir	ng the past		
Prosess Duams FY-82: At the	November 13th mee	ting of t	he PVSG thi	is study was		
closed to further patient the minutes of that meeti	accrual. No new	data wil	ll be fortho MC patients	coming until were entered.		
Huram of Subjects Sidelies:	ing are passioned					
FY-82: NONE TOTAL (TO DATE): NONE	BEFORE	COMPLETION OF	STUDY: NONE		
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF HOME SO STATE): NONE						
Concessions: Hydroxyurea (HU) appears to be a	useful a	ment in the	promot and		
continuous concret or migh	i braceset conics	THE DE THIS	ry curdinoc	ytosis without		
significant toxicity. Let continued followup of the						
leukemogenic potential for	r this drug is fel	t to be				
akylating agents used to Publications of Asstracts, FY-82		se.				
FUSCICATIONS OF MESTRACIS: F1-02	: NONE					

D _{ATE} :15 Dec 82	HORK LINET N	o.: 1007	STATU	S: INTERIM	X FINAL	
STARTING DATE:	1 Nov 80		DATE OF COMPLE	FION: 1 Nov	83 (estima	ted)
KEY HORDS: Subur	nit combina	tion, hormon	ne action, h	man chorio	nic gonadot	ropin
TITLE OF PROJECT:	The Role of the S	of Carbohy Subunits of	drate Moietic	es in the Conic Gonadot:	ombining Pro	operties
PRINCIPAL INVESTI	GATOR(S): (IAJ Henry G. COL Richard	Fein, LTC Ro	obert Small:	ridge,	
ASSOCIATE INVESTI	GATOR(S):					
FACILITY: HRANC		DEPT/SVC:	Dept of Med	icine/Gener	al Medicine	Svc
Accumulative MEDC 7920	ASE Cost:		CONTRACT COST: 200	ACCUMULATIV 26:57	E SUPPLY COST: 72	
FY-83 /EDCASE:	CONTRACT COST	T: Supply Cost		F COMMITTEE AP PROGRESS REPO	PROVAL OF RT FEB 26	_1982
STUDY OBJECTIVE: determine the hormone. TECHNICAL APPROAC			arbohydrate s to combine e further si			
role of carbon						
		ors. Lawrence	e Cole and R	obert Hussa	at the Med	ical College (cont.)
PROGRESS DURING F		DoT and Cas	Ki cella do.	in fact. p	roduce hCG	• • • •
moieties t Number of Subject	<u>hat retain</u>	biological	activity, in	the sense	that they a	re able to (cont.)
FY-82: 0	TOTAL	(TO DATE):	O Bef	DRE COMPLETION	OF STUDY: NO	ne
SERIOUS/UNEXPECTE	D SIDE EFFECTS	IN SUBJECTS PA	ARTICIPATING IN	PROJECT(IF NON	E SO STATE):	None
CONCLUSIONS:						
See PROGRESS D	URING FY-8	2				
PUBLICATIONS OR A	BSTRACTS . FY-	32:				
None.						

WORK UNIT NO.: 1007

TECHNICAL APPROACH:

of Wisconsin, we have continued to examine the combining properties of various forms of affinity-purified hCG beta produced ectopically by the DoT and CasKi lines of human cervical carcinoma cells. We have examined the hCG so produced by specific radioimmunoassay and a rat testis radioreceptor assay.

2. We have continued our studies of the combining properties of standard hCG subunits before and after treatment with mixed exoglycosidases which putitively removed greater than 80% of the carbohydrate from these glycoproteins. We have extended these studies and have done multiple control experiments to try to rule out the presence of contaminating species that might inhibit combination.

PROGRESS DURING FY-82:

combine with standard hCG alpha to produce hCG molecules that are active in both radioimmunoassay and radioreceptor assay systems. Shortly before we were to publish these results, Hussa and co-workers demonstrated a rather remarkable finding. Further purification by ion exchange and affinity chromatography demonstrates that ectopic hCG-beta can be distinguished into two forms. One was indistinguishable from standard hCG-beta while the other, although larger on gel chromatography, lacked the characteristic COOH-terminal peptide (CTP). This was shown by the failure of antisera specific for determinance on the CTP to recognize this molecule and by the apparent absence of the O-linked oligosaccharides and thermolysin cleavage site normally found in this region. (Cole, Birken, Sutphen, Hussa and Pattillo: Endocrinology 110: 2198-2200, 1982) We, therefore, have begun the large scale production by these cells of ectopic hCG beta in hopes to purify large (200-300 ug) amounts of each form of hCG-beta to study both the combining properties as well as the chemistry of these forms. Furthermore, once the cells are harvested, they will be sent to Dr. Irving Boime (Washington University, St. Louis) for eventual studies of the genome of these cells.

2. Although we have been able to demonstrate that deglycosylation of the hCG subunits greatly inhibits the ability of the subunits to combine with the opposite fully glycosylated subunit using two entirely different sets of exoglycosidases, we have had difficulty demonstrating that control experiments (in which the hCG subunits were similarly handled but were not deglycosylated) did not result in similar inhibition of combination.

DATE: 15 Dec 82 How WHIT N	o.: 1008	STATUS: INTERIN X FIRM						
START 1:3 DATE: 1 NOV 80	rici: 1 Nov 83 (estimated)							
Key kees: Thyroid hormone action, Nuclear receptors, Fibroblasts								
TITLE CF PROJECT: Mechanism	TITLE CF PROJECT: Mechanisms of Thyroid Hormone Resistance							
		•						
MAJ PRINCIPAL INVESTIGATOR(S):	Henry Fein, LTC R	obert C	C. Smallridge, COL Richard C. Dimond					
ASSOCIATE INVESTIGATOR(S):	·							
FACILITY: HRAYE	DEPT/S/C: Dept	of Med	icine/General Medicine Service					
ACCUPALATIVE PECCASE COST:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE SUPPLY COST:					
7920	0		31,910					
FY-83 PECCASE: CONTRACT COS	T: Sipply Cost: 10,000	VATE OF PANUAL	F COMMITTEE APPROVAL OF PROGRESS REPORT FEB 2 6 1982					
			alities associated with thyroid esseretion of thyrotropin (TSH)					
TECHNICAL APPROACH: During	FY-82 we completed	studie	es of nuclear thyroid hormone					
receptors and fibroblast	s taken from the s	kin of	normal patients and patients with ktensive studies of thyroid hormone (cont.					
PROSESS DURING FY-82:	ice. we also condu	CCCG CA	(cont.					
We demonstrated that the	ere are no signific	ant abi	normalities in nuclear receptor					
number or affinity when hurses of Susucors Studied:	whole cells are st	udled	for triiodothyronine binding, (cont.)					
25.00. 62. 20.10. 0.103.								
Serious/Unexpected Side Effects in Subjects Participating in Project(if home so state): None. (Fibroblasts were harvested from a number of otherwise discarded foreskin samples obtained after circumciation by the Obstetrics Service.)								
Conclusions:	·		JELY JELY					
SEE PROGRESS DURING FY-	82.	•						
-								

PUBLICATIONS OR ASSTRACTS. FY-82:

Publication:

Eil, C, Fein HG, Smith TJ, et al, Nuclear binding of 125 I triiodothyronine in dispersed cultured skin fibroblasts from patients with resistance to thyroid hormone. J Clin Endocrinol Metab 1982; 55: 502-510.

Publications and Abstracts FY-82 Worked on in Collaborative Study Performed at Kimbrough Army Hospital, Ft. Meade, MD, under an HSC-Approved Clinical Investigation Protocol:

Fitz JD, Sperling EM, Fein HG, Long-term treatment of obese diabetics with semistarvation diet. Slide presentation at the 3rd Annual Meeting of the Society of Military Endocrinologists, San Francisco, CA, June, 1982. WORK UNIT NO.: 1008

TECHNICAL APPROACH:

action in cultured fibroblasts from normal patients exposed to normal and reduced concentrations of thyroid hormone in the medium.

PROGRESS DURING FY-82:

comparing normals to patients with thyroid hormone resistance. In studies of specific binding of radio-labeled thyroxine to nuclear receptors, we determined that that this species was most likely triiodothyronine converted intracellularly and not direct binding of thyroxine. We attemted to demonstrate specific abnormalities of glucose utilization, lactate formation, 2-deoxyglucose uptake and uridin incorporation into whole cells and cell protein in fibro-blasts obtained from normal subjects exposed to normal and to reduced levels of thyroid hormone. In three sets of experiments in our laboratory and another set of experiments consisted at the National Naval Medical Center by Dr. Judy Fradkin, we were unable to demonstrate any decrease in metabolic function in cells grown in thyroid hormone depleted medium. We are, therefore, embarking on two other lines of investigation. First, we will study a membrane phenomenon, the presence of beta adrenergic receptors (both number and affinity by Schatchard analysis) and Malic enzyme activity in fibroblasts grown in medium containing excess and deficient amounts of thyroid hormone.

DATE: 1/19/83 Nox UNIT NO	.: 1009 STATUS	s: Interin Firm X	
STARTILE DATE: 5 Februar	y 1982 DATE OF COMPLET	icii: 31 December 1982	
Key Nords: Urinary Trac	t Infection. Role o	f ultrasound & CT Scanni	n g
TITLE OF PROJECT: SEVERE	URINARY TRACT INFECT	CION. THE ROLE OF	
ULTRASOUND AND COMPUT			
TRINCIPAL INTESTICATION	Carl June		
ASSOCIATE INVESTIGATOR(S):	Leonard M. Checchio		
FACILITY: WRANC	DEPT/Syc: Medicin	le	
ACCURALATIVE MEDICASE COST:	ACCUMPLATIVE CONTRACT COST:	ACCUMULATIVE SUPPLY COST:	
FY-83 PECCASE: CONTRACT COST	: SUPPLY COST: DATE OF FRINDAL	COMMITTEE APPROVAL OF PROGRESS REPORT FEB 2.5 1982	
urinary tract infecti		ound in management of	
TECHNICAL APPROACH: Ultrasou with severe urinary t	· ·	ormed on patients admitt	e d
Peoples Busing FY-82:	two patients fit cri	teria and were entered	
Mursex of Subjects Studied:			
	TO DATE): 2 pts at WRAMO		
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	IN SUBJECTS PARTICIPATING IN P	ROJECT(IF HOME SO STATE):	
Conclusions: These two pa at Bethesda. Findin	tients will be added gs are now being pro	to the pool of subjects cessed.	
PUBLICATIONS OR ABSTRACTS, FY-82	: NONE		

STARTILE DATE: 1 Aug 82	5.: 1010 Day	Status: Interin X Firm E or Connection: 30 July 85 (estimat
Key logos: Thyroiditis, g	goiter, hypothyro	oidism, HLA typing
Title CF PROJECT: Longitudi	inal Studies of I	Postpartum Lymphocytic Thyroiditis
	•	I MC and Thomas A. Klein COL MC
ASSOCIATE INVESTIGATOR(S): KI		
FACILITY: KRAIC	DEPT/SVC: De	ept. of Medicine/General Medicine Sept of Obstetrics and Cynecology
ACCUPARATIVE PEDCASE COST:	ACCUPALATIVE CONTR	ACT COST: ACCUMULATIVE SUPPLY COST:
FY-83 PEDCASE: CONTRACT COS	ST: SUPPLY COST: \$500	DATE OF COMMETTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 & 198
TECHNICAL APPROACH: During (1) we have begun to ent	coll obstetric pa	rmine appropriate means for screens we began this study in 2 different atients, who have delivered here a
TECHNICAL APPROACH: During (1) we have begun to enr for a prospective study PROSRESS DURING FY-82: thyroi Preliminary steps were i Technical Approach, and	roll obstetric parts of to determine the determine the dittis in an unselection beginstituted to beginstituted to beginstituted.	we began this study in 2 different atients, who have delivered here a <u>incidence and severity of lymphoc</u> elected population. (continued on p gin these studies as delineated und
(1) we have begun to enr for a prospective study PROSERSS DURING FY-82: thyroi Preliminary steps were i Technical Approach, and HUMBER OF SUBJECTS STUDIED:	roll obstetric parts of to determine the determine the dittis in an unselection beginstituted to beginstituted to beginstituted.	we began this study in 2 different atients, who have delivered here a <u>incidence and severity of lymphoc</u> elected population. (continued on p gin these studies as delineated und
TECHNICAL APPROACH: During (1) we have begun to enr for a prospective study PROSRESS DURING FY-82: thyroi Preliminary steps were i Technical Approach, and Number of Subjects Studied: FY-82: 6 Total	to determine the ditis in an unsensituted to begathe first patier (TO DATE): 6	we began this study in 2 different atients, who have delivered here a <u>incidence and severity of lymphot</u> elected population. (continued on p gin these studies as delineated und ats were enrolled.
TECHNICAL APPROACH: During (1) we have begun to enr for a prospective study PROSESS DURING FY-82: thyroi Preliminary steps were i Technical Approach, and NUMBER OF SUBJECTS STUDIED: FY-82: 6 Total Serious/Unexpected Side Effect None.	to determine the ditis in an unsensituted to begathe first patier (TO DATE): 6	We began this study in 2 different atients, who have delivered here are incidence and severity of lymphocalected population. (continued on pain these studies as delineated undata were enrolled. Before Completion of Study: 250
TECHNICAL APPROACH: During (1) we have begun to enr for a prospective study PROGRESS DURING FY-82: thyroi Preliminary steps were i Technical Approach, and NUMBER OF SUBJECTS STUDIED: FY-82: 6 TOTAL SERIOUS/UNEXPECTED SIDE EFFECT	to determine the ditis in an unsectituted to beginstituted to beginstituted to begins (TO DATE): 6	We began this study in 2 different atients, who have delivered here are incidence and severity of lymphocalected population. (continued on pain these studies as delineated undata were enrolled. Before Completion of Study: 250
TECHNICAL APPROACH: During (1) we have begun to enr for a prospective study PROGRESS DURING FY-82: thyroi Preliminary steps were i Technical Approach, and NUMBER OF SUBJECTS STUDIED: FY-82: 6 TOTAL SERIOUS/UNEXPECTED SIDE EFFECT None. CONCLUSIONS:	to determine the ditis in an unsectituted to beginstituted to beginstituted to begins (TO DATE): 6 S IN SUBJECTS PARTIC	We began this study in 2 different atients, who have delivered here are incidence and severity of lymphocalected population. (continued on pain these studies as delineated undata were enrolled. Before Completion of Study: 250
TECHNICAL APPROACH: During (1) we have begun to enr for a prospective study PROSRESS BURING FY-82: thyroi Preliminary steps were i Technical Approach, and HUMBER OF SUBJECTS STUDIED: FY-82: 6 TOTAL SERIOUS/UNEXPECTED SIDE EFFECT None. TOMOLUSIONS:	to determine the ditis in an unsectivated to beginstituted to beginstituted to beginstituted. (TO DATE): 6 S IN SUBJECTS PARTICE: al Year 1982.	We began this study in 2 different atients, who have delivered here are incidence and severity of lymphocalected population. (continued on pain these studies as delineated undata were enrolled. Before Completion of Study: 250

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Technical Approach (cont) (2) In association with Dr. T. Nikolai of the Marshfield Clinic, Marshfield, Wisconsin, and Dr. C. Johnson of the Lombardi Cancer Research Center, Georgetown University Medical Center, we have begun HLA typing to determine the gene frequencies present in patients with postpartum lymphocytic thyroiditis, spontaneously resolving thyroiditis not associated with pregnancy and a control population with classical Hashimoto's disease.

DATE: 15Sept82 Mage Unit N	0.: 1011	Status: Interim	Firal	
STARTING DATE: 1 Aug 82	DATE OF	CONSTRUCTION: 30 July	83	
Key Horas: Polymyositis,	Therapeutic Exercis	e. Muscle Enzymes		
TITLE OF PROJECT: Effect of Patients with Polymyosit		ise on Muscle Enzy	nes in	
PRINCIPAL INVESTIGATOR(S): P	eter R. Levine, M.D	., MAJ, MC USA		
ASSOCIATE INVESTIGATOR(S): Mi	chele Wineland, R N	. M.S.N. Noreen I	Rossi, M.P.T.	, CPT AMSC
FACILITY: MRAYE	f ·	ine/General Medici		IIC A
ACCUMULATIVE PEGCASE COST:	ACCUMULATIVE CONTRACT			G J
	T: SUPPLY COST:	DATE OF COMMITTEE APPR ANNUAL PROGRESS REPORT	OVAL 07 FEB 2 5 1982	
STUDY OBJECTIVE: To assess		gle exercise session	on on muscle	enzyme
levels in patients with				
TECHNICAL APPROACH: Recover session under supervision	ing, ambulatory pat n. Pre-exercise, 4	ients perform a mil -hour and 24-hour	ld, isometric post-exercise	exercise CPK
and aldolase levels are	measured. Protocol		ild calisthen:	
PROGRESS DURING FY-82: Three are scheduled to partici	patients have comp	leted the protocol		
Murber of Subjects Studied:	•			
FY-82: 3 TOTAL	(TO DATE): 3	BEFORE COMPLETION O	F STUDY: 20	
SERIOUS/UNEXPECTED SIDE EFFECTS None	S III SUBJECTS PARTICIPAT	ING IN PROJECT(IF NONE	SO STATE):	
Conclusions: Insufficient	number of patients	studied to make con	nclusions.	
			_	
PUBLICATIONS OR ABSTRACTS, FY-	S2:			
None				

	DATE: 7 Oct 82 HORK UNI	r No.: 1121		Status	: INTERINXXX	FINAL	
	STARTING DATE: Extended	2/79	DATE	OF COMPLET	ion: expecte	d 2/84	
	Key liopos plasmapheres is	, glomerul	onephriti	s, cytot	oxic agents		
in t	TITLE CF PROJECT:Combined the treatment of anti-g						
	PRINCIPAL INVESTIGATOR(S)40	hn P. Johr	ison, MD,	LTC, MC	Jack Moor	e, Jr. MD, I	MAJ, MC
	ASSOCIATE INVESTIGATOR(S):	NONE		·			_
	FACILITY: HRAYC	t t	т/Svc: Med i	cine/ Ne	phrology		•
	Accumulative PEDCASE Cost:	ACCUMULA	TIVE CONTRAC	τ Cosτ:	ACCUMULATIVE S	SUPPLY COST:	•
	FY-83 I'EDCASE: CONTRACT	Cost: Suppl	y Cost:	DATE OF	COMMITTEE APPROPRIES REPORT	FEB 2 5 1902	· }
wit! and	STERN OBJECTIVE TO COMPAR Prasma exchange on th the effect of this on TECHNICAL APPROACH Patient	modifying	disease c	ourse.			
ran	iomized to RX with eith	er pred/cy	ytoxan alo	ne or in	n combination	with plasma	a exchange
Disa	ppearance rates of ab	will be ca	alculated nations	and comp	pared along w	ith clinica	l outcome two of which
wer	Process Dualing FY-82: A to entered in FY 82. Ana	lysis of t	the data a	t this	point suggest	s a more ra	pid dis-
a pp	earance of ab in the pl	asma excha	ange group	, with a	more favora	ble clinica	l outcome
	Munsea of Subjects Studied:						
	FY-82: 2 To	TAL (TO DATE)	: 17	Befo	RE COMPLETION OF	= STUDY: 30	
	SERIOUS/UNEXPECTED SIDE EFFI no serious or unexpect	ed side et	ffects hav	e occurr	red so far		•
a mo ab wit	CONCLUSIONS: More patient sions can be drawn stated by the favorable clinical disappeaance rates are the NIH and with FAMO patient population.	outcome is more rapid	s achieved d with pla	i via the sma excl	e use of plas nange. We con	ma exchange tinue to co	, and that llaborate

Publications or Abstracts, FY-82: An abstract delineating our results has been submitted and selected for presentation at the 14th Annula Meeting of the American Society of Nephrology, December, 1982, in Chicago, Il. A copy of this abstract is attached.

DATE: 14 Sep 82 HOPK UNIT N	0.: 1]24	STATUS: INTERIM	From X						
STARTING DATE: December 19	77 DATE OF	COMPLETION: September	er 1982						
Key Words: Chronic Renal Failure, Hyperuricemia, Rate of Progression									
TITLE OF PROJECT: "The Effect of Hyperuricemia on Chronic Renal Failure"									
PRINCIPAL INVESTIGATOR(s): Daniel A. Nash, Jr., MD, COL, MC									
ASSOCIATE INVESTIGATOR(S): N	one								
FACILITY: NRAYE	DEPT/Svc: Depar	tment of Medicine/No	ephrology Service						
ACCUMULATIVE PEDCASE COST:	ACCUMBLATIVE CONTRACT	COST: ACCUMULATIVE S	UPPLY COST:						
FY-83 I'EDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPROAUML PROGRESS REPORT	VAL 0.5 2 5 1982						
STUDY OBJECTIVE: To determine if hyperuricemia occurring in patients with chronic renal failure from other causes is a deleterious factor in the progression of their renal failure. TECHNICAL APPROACH: Patients with progressive chronic renal failure and significant hyperuricemia will be prospectively followed until they enter hemodialysis or kidney transplantation. They will be randomized into groups whose hyperuricemia is untreated progress During FY-82: the two groups, and before and after entering the study. Protocol remained inactive during FY 82									
MUMBER OF SUBJECTS STUDIED:									
FY-82: 0 TOTAL	(TO DATE): 4	BEFORE COMPLETION OF	Sтиру: 20						
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE): NONE									
CONCLUSIONS: Protocol will not be continued because of limited availability of suitable patients, and no support personnel to assist with patient location and longitudinal follow-up. Further, I foresee no probability of altering either of these limiting factors. Therefore, no conclusions could be drawn from data obtained. Publications or Abstracts, FY-82: NONE									
I APPTICULT OF UDSTANCISY LIE	~ HUNE								

	DATE: 15 Nov 82	Hose Unit No.	: 1127	STATUS: IN	TERIN	FIGUR X			
	STARTILE DATE:	June 1979	DATE O	F COMMETICAL	15 Novembe	r 1982			
•	KEY LORDS: Borderline Hypertension, Prospective Follow-up TITLE CF PROJECT: "Characterization and Response to Therapy in Mild Essential Hypertension" Daniel A. Nash, Jr., MD, COL, MC PRINCIPAL INVESTIGATOR(S): Joyce Patrick, RN, CPT, ANC ASSOCIATE INVESTIGATOR(S): Betty Watkins, RN, MAJ, ANC								
	FACILITY: WRAYE DEPT/S/c: Medicine/Nephrology/Nursing Service								
	ACCURATIVE PER	ASE Cost:	ACCUMALATIVE CONTRACT	COST: ACC	UMULATIVE SU	PPLY COST:			
	FY-83 PEDCASE:			ANNUAL PROGR		FFR 2.5 1001			
rocedures Response P	STUDY OBJECTIVE: lasma Henin) ma	To systemic tively, to ailable to the used to	cally follow-up p evaluate their n ne practioner, (i predict outcome	atients with atural histo .e. ECG. Ect . and to de	h borderling ory. To de hocardiogra termine the	he hypertens etermine if am Isometri impact or	ion prospec- certain c Stress weight reduc		
evaluation and changes and s	to include rer d isometric exe odium restricti	Patients in activity rcise will ton as would	cally follow-up pevaluate their nee practioner. (io predict outcome ens. s with borderline ECG Echocardio de determined. Per standard para and rate of developments and rate months.	hypertensic gram. Blood atients wil ctice. The:	on will red d pressure l be treate se with fac	cieve a comp response to ed with weig ctors will b	lete medical positional treduction considered		
into the s to continu	e the study no uring the remains	further enti	y-three patients east 6 months. Bries into the pro	with border ecause tocol will be referred	line hyperinvestigate be accepted for follow-	tension have ors will not i. The data oup through	been entere be able will be other source		
•	Hurger of Subject	रड शिकाद्यः					•		
	FY-82: 6	TOTAL	(TO DATE): 23	BEFORE CO	SO KOITBLYSK	STUDY: 23			
	SERIOUS/UNEXPECT	ED SIDE EFFECTS	IN SUBJECTS PARTICIP	ATING IN PROJEC	t(if home so	STATE): None	:		

CONCLUSIONS: Data will be analyzed to determine if correlation can be obtained from the small number of patients entered into the study with respect to the importance of dietary salt weight reduction, plasma renin activity, orthostatic posturing, isometric exercise, blood pressure response, ETC. On the incidence of development of fixed hypertension in patients initially diagnosed as having borderline hypertension. It is probable that limited conclusions can be drawn as a consequence of the small number of entries into the study.

PUBLICATIONS OR ASSTRACTS. FY-82: FUBLICATIONS OR ASSTRACTS. FY-82: None at the present time, any that evolve in the future will be made known to the Clinical Investigation Service for the purpose of ammending this final report.

DATE:11 Nov 82	North Ever N	o.: 1128	STATUS	: Interim X	Fire	
STARTING DATE: June 1979 DATE OF COMPLETION: Undetermined					•	
KEY CROS: End-stage Renal Disease, Rehabilitation, Activity Monitoring						
TITLE CF PROJECT: "Evaluation of the Rehabilitation of End-stage Kidney Disease by Hemodialysis and Kidney Transplantation Using Activity Recording"						
PRINCIPAL INVESTIGATOR(S): Gregory Belenky, MD						
ASSOCIATE INVESTI	GATOR(S): Jin	nmy Light, MD,				
FACILITY: WHAIR	Neuropsychi	atry DEPT/S:C: Psych	iatry/0	rgan Transpla	ntation	
Accumulative PEGG	ASE Cost:	ACCUMULATIVE CONTRACT	r Cost:	ACCUMULATIVE	SUPPLY COST:	
FY-83 MEDCASE:		r: Supply Cost:	KUNUAL	COMMETTEE APPRI PROGRESS REPORT	FEL 2 6 1982	ı ,
STUDY OBJECTIVE:	To monitor prior to ar modes.	activity of patiend after being tre	nts with ated by	n end-stage r several reha	enal disease bilitation	.
TECHNICAL APPROACH: A movement monitor (actigraph) will be place on patients with end-stage renal disease and are in imminent need of hemodialysis or kidney transplantation. Baseline activity will be compared to repeat determination of activity after end-stage renal disease therapy. The difference in activity will be transplantation of rehabilitation.						
Third compacity, and representation	generation reproduc - a and interpt	actigraph has been billity. In house ation of data. A	n develo	oped with imper programing	roved sensit has been co lave been st	ivity impleted for idled.
HUMBER OF SUBJECTS	: ड्याकार					
FY-82: 4	TOTAL	(TO DATE): 7	BEFO	RE COMPLETION OF	STUDY: 20-40)
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF HOME SO STATE): None						
CONCLUSIONS: NO	ne	· · · · · · · · · · · · · · · · · · ·				
			•			
Pure trations of Agerparte FV-87. None						

	Principal Investigator(s): Suzann Associate Investigator(s): NONE		Jack Moore, Jr. MD,
Ī	ACILITY: KRAYE	Dept/Syc Medicine/ Neg	phrology
_	COUNTRATIVE PEDCASE COST: AC	CUMBLATIVE CONTRACT COST:	ACCUMULATIVE SUPPLY COST:
F	Y-83 PEDCASE: CONTRACT COST:	Supply Cost: Date of Remual	F COMMITTEE POROVAL OF PROGRESS REPORT FE 25 198
	ROSRESS Russurs FY-82: NONE	·	
	terser of Subjects Studied: Y-82: NONE Total (To	DATE): 6 BEFO	RE COMPLETION OF STUDY:
S	ERIOUS/UNEXPECTED SIDE EFFECTS IN NONE	SUBJECTS PARTICIPATING IN P	ROJECT(IF NONE SO STATE):



DATE: 7 NOV 82 NOW UNIT	No.: 1130	STATUS: INTERIN X FIRE				
STARTING DATE: 08 April 1980 DATE OF COPPLETION: April 1984						
Key Nephrotoxicity, Radiocontrast Agents, Uric Acid						
TITLE OF PROJECT: "THE ROLL	TITLE OF PROJECT: "THE ROLE OF HYPERURICOSURIA IN THE NEPHROTOXICITY OF					
RADIOCO	RADIOCONTRAST AGENTS"					
PRINCIPAL INVESTIGATOR(S): JACK MOORE, JR., MD, MAJ, MC						
ASSOCIATE INVESTIGATOR(S):						
FACILITY: NRAYE	DEPT/Syc: Dept	. of Medicine/Nephrology	Service			
Accumulative MEBCASE Cost:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY CO	OST:			
FY-83 PECCASE: Contract Co	DIST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2	5 1983			
STUDY OBJECTIVE: To determine if the incidence of, or severity of RC induced ARF can be attenuated by pre-RC therapy with volume expansion.						
·		idomly assigned to one of a cential blood and urine te				
PROSRESS DURING FY-82: 4 1						
Humaen of Subjects Studied:						
	L (TO DATE): 32	BEFORE COMPLETION OF STUDY:	50			
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NOME SO STATE): NONE						
Conclusions: Preliminary data analysis suggests that there are no differences in renal outcome in the 3 treatment groups.						
PUBLICATIONS OR ABSTRACTS, FY	-82:					
• • • • • • • • • • • • • • • • • • • •		ty: Relationship With Uri	С			

Clinical Research 30(2): 449A, 1982.

DATERS NOV 82 Mark Unit No.: 1131	STATUS: INTERIM FIRM X					
START :: DATE: November 1979 DATE OF	CONFLETION: November 1982					
Key logos: Coumadin Therapy, hematuria, Urine Urokinase Activity						
TITLE CF PROJECT: "Hematuria During Antiocoagualation Therapy With Coumadin"						
PRINCIPAL INVESTIGATOR(S): Daniel A. Nash, Jr., MD, COL, MC, Chief, Nephrology Svc.						
ASSOCIATE INVESTIGATOR(S):						
FACILITY: IRAY DEPT/Syc: Depart	tment of Medicine/Nephrology Svc.					
ACCUMENTATIVE PEDCASE COST: ACCUMENTATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:					
FY-83 PEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983					
STUDY OBJECTIVE: To determine the incidence of microscopic hematuria in patients on standard Coumadin therapy. To determine etiology of hematuria when it occurs in such patients. To determine if urine urokinase is abnormal in such patients. TECHNICAL APPROACH: Patients recieving Coumadin for standard indications and standard dosages will be screened for the presence of microscopic hematuria. Those determined to have hematuria on repeat examination and in the absence of Coumadic over-anticoagulation will be further evaluated for causes of hematuria. Futhermore, urine urokinase activity will be determined to see if this urinary antiocoagulant is PROSESS BREWS FY-82: abnormal in such patients. No additional patients were added to the protocol during FY-82. Efforts were made to establish a meaningful urine urokinase activity. However, all efforts to obtain a reasonably reliable assay were disappointing. This aspect or the protocol was dispendingly and no further attempts were made to obtain the urokinase assay at this time. FY-82: 0 Total (TO DATE): 66 BEFORE COMPLETION OF STUDY: Discontinued Serious/Unexpected Side Effects in Subjects Participating in Project(if home so state): None						
DMCLUSIGNS: Observations would suggest that have an incidence of hematuria as high as 10 findings by standard urological work-up. Be evaluated it is possible that our findings of cance. Information with respect to this sign be determined.	t patients on standard dose Coumadin may 0% in the absence of any pathological ecause of the low number of patients will not obtain a high degree of signifignificance of urinary urokinase could not					

FUBLICATIONS OR ASSTRACTS. FY-82: None. If any information is determined for the publication after final analysis of all data generated, this will be submitted to Clinical Investigation Program for ammendment of this final progress report.

DATE: 16 NOV 82 HORE LINET HE).: 1132	STATUS: INTERIM	x From	_		
STARTING DATE: July 1980 DATE OF CONFLETION: Undetermined						
Key North IgA Nephropathy: A Perspective Study						
TITLE CF PROJECT: Ig A Nep	hropathy: A Pr	ospective Eva	aluation			
		•		-		
PRINCIPAL INVESTIGATOR(S): Steven F. Gouge, MD, CPT, MC, Fellow in Nephrology						
ASSOCIATE INVESTIGATOR(S): Jac	k Moore, Jr., MD,	MAJ, MC, Asst.,	Chief Nephrolo	<u>e</u> y		
FACILITY: KRAYE	DEPT/SVC: Depar	tment of Medici	ne/Nephrology S	ervice		
ACCUPALATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Cost: Accumula	TIVE SUPPLY COST:	•		
FY-83 PEDCASE: CONTRACT COS	T: Supply Cost:	DATE OF COMMITTEE ANNUAL PROGRESS R	APPROVAL OF EPORT FF 1 2 5 100	-		
	mine pathologic and					
Suitability for military	thy, the prognosis service, the exten	of patients wit t of evaluation	h the diagnosis and the degree	and their of follow-up		
TECHNICAL APPROACH: Patients	witha biopsy prov	en diagnosis of	IgA Nephropath	y will be en-		
TECHNICAL APPROACH: Patients rolled in the study. The sed rate, HLA typing, Ig. Follow-up will be every thanks study typing a company of the sed rate.	By Will have basell A coated Lymphocyte Six months with a U	s, serum IgA le	evels, and skin serum creatin	biopsy.		
PROSESS TURYER FY 82: a comp.	lete history and ph w patients enrolled	ysical.	v	<u>o</u> , 50.0108100		
in ee ne	· paulonus em offe	i into one soud,	, .			
Hursen of Subjects Studied:						
FY-82: 3 TOTAL (TO DATE): 16 BEFORE COMPLETION OF STUDY: 40						
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF HONE SO STATE): None						
CONCLUSIONS: No conclusion	ns can be reached a	s of vet. dut t	he small number			
and the shor	t follow-up time. data processing mo	Preliminary and	alysis of data :			
<i>.</i>			•			
PUBLICATIONS OR ABSTRACTS. FY-	82: None			•		

DATE: 16 NOV 82 MORE UNIT NO.: 1133 SUS: INTERIN X FIRM							
STARTING DATE: July 1980 DATE OF Concerning: Undetermined							
Key Coos: Hematuria, Urokinase, Lysed Red Blood Cell Culture, HLA typing, Skin Biopsy							
TITLE CF PROJECT: Primary Renal Hematuria: A Prospective Study							
PRINCIPAL INVESTIGATOR(S): Steven F. Gouge, MD, CPT, MC, Fellow Nephrology Service							
ASSOCIATE INVESTIGATOR(S): Jack Moore, Jr., MD, MAJ, MC, Asst., Chief Nephrology Service							
FACILITY: WAYC DEPT/Syc:Department of Medicine, Nephrology Service							
ACCUMULATIVE PEDCASE COST: ACCUMULATIVE CONTRACT COST: ACCUMULATIVE SUPPLY COST:							
FY-83 PEDCASE: CONTRACT COST: SUPPLY COST: DATE OF COUNTITIES REPORT FEB 2 5 1983							
STUDY OBJECTIVE: To determine the etiology and significance of hematuria, as well as prognosis without a prior history of renal or systemic disease. In this respect, clin cal pathological correlatations will be made with conclusions drawn concerning appropriate extent of medical evaluation. TECHNICAL APPROACH: Patients which qualify for the protocol will have renal arteriograms renal biopsies, skin biopsies, urine urokinase, HLA typing, IgA coated Lymphocytes, lysed red blood cell cultures preformed. PROSRESS DURING FY-82: Six new patients enrolled in the study.							
Humber of Subjects Studied:							
FY-82: 6 TOTAL (TO DATE): 24 BEFORE COMPLETION OF STUDY: 50							
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NOME SO STATE): Nome							
CONCLUSIONS: No conclusions reached as yet. Preliminary analysis of data is planned when data processing money becomes available.							
·							
Publications or Asstracts, FY-82: None							

DATE: 24 NOV 82 HOW WHIT M	o.: 1134	STATUS	: Interin	Fran X	
STARTING DATE: 18 September 1980 DATE OF COMPLETION: 24 November 1982					
Key Keys: Catecholamines, Opioid Peptides, Hemodialysis					
TITLE CF PROJECT: "Catecholamines, Opioid Peptides, and Hemodialysis"					
		•			
PRINCIPAL INVESTIGATOR(S): Jo	mmes R. Cain, MD ohn B. Copley, MD a	nd C. I	Raymond Lake	e, MD	
Associate Investrgator(s): L. Harrison Hassell, MD					
FACILITY: KRAYE	DEPT/Syc: Nephro	logy		•	
ACCUMULATIVE PEDCASE COST:	ACCUMALATIVE CONTRACT			SUPPLY COST:	
FY-83 MEDCASE: CONTRACT COST	T: Supply Cost:	DATE OF AMMUAL	COMMITTEE APP PROGRESS REPOR	ROVAL OF 2 2 1362	>
STUDY OBJECTIVE: To determine the level of plasma catecholamines and opioid peptides during hemodialysis and ultrafiltration.					
TECHNICAL APPROACH: Serial sapeptides during variations	amples of blood dra s of dialysis and u	wn and ltrafi	assayed for ltration.	catecholamin	es and
PROGRESS DURING FY-82: None					
·					
HUMBER OF SUBJECTS STUDIED:					
FY-82: 0 TOTAL (TO DATE): 10 BEFORE CONSLETION OF STUDY: 20					
SERIOUS/UNEXPECTED SIDE EFFECTS	IN SUBJECTS PARTICIPAT	ins in Pi	ROJECT(IF HONE	SO STATE): None	•
Conclusions: No conclusions of inability to obtain ade investigators.	reached to date. equate assays and l	Projection	et will be d interest on	iscontinued be the part of i	ecause intended
Publications or Asstracts, FY-82: None					

				
DATE: 1 Feb 83 MORK UNIT NO.	:1135	STATUS:	INTERIM XX	Fire
START IT BATE June 1981	COMPLETI	ON: June 198	4	
Key Noras: Oliguric ARF, F	urosemide, ARF pro	phylax	is	
	f Furosemide in Ea			Failure
•		·		
PRINCIPAL INVESTIGATOR(S): Ja	ck Moore, Jr. MD,	MAJ, M	C Asst, C	, Nephrology
ASSOCIATE INVESTIGATOR(S): Fe	llows, Nephrology			
FACILITY: WRAYC	DEPT/Svc: Medici	ne/ Ne	phrology FEB	2 5 1983
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Созт:	ACCUMULATIVE	SUPPLY COST:
FY-83 FEDCASE: CONTRACT COST 0 0	: Supply Cost:	DATE OF	COMMITTEE APPRI PROGRESS REPORT	DVAL OF
STUDY USUACTIVE To determine the outcome of early olig TECHNICAL APPROACHINY patient prement and postrenal ca	uric renal failure	?		
p rerenal and po strenal ca neceive graded doses of f	uses have been rul urosemide in seque	ed out ence. w	, will rando ith control	mly assigned to pts. receiving sali
Process Province EV-82+	despite appeal to	servi	ce and depar	tment chiefs,
as experimental. Number of Subjects Studies:				
	(TO DATE): 0	BEFO	RE COMPLETION O	F STUDY: 40
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	IN SUBJECTS PARTICIPAT	ing in Pi	ROUECT(IF NONE	SO STATE):
CONCLUSIONS: We believe tha needs to be answered. The considered experimental. different circumstances, CIS can give us in solici	routine use of hi Indeed, several si to be ineffective.	igh dos tudées . We wo	e furosemide have shown i uld apprecia	should be t, under slightly te any help
PUBLICATIONS OR ABSTRACTS, FY-8	2:			

DATE 29 NOV 82 NOW LINET	fio.: 1137	STATUS:	Interin X	Fire		
STARTILE DATE: 01 April 1981 DATE OF COMPLETICH: Undetermined						
Key leas: Uremia, Chronic Renal Failure Anemia						
TITLE CF PROJECT: "The Rol Cell (RBC) Deformability	`	<u> </u>		e on Red Blood al Failure"		
Jack Moore, Jr., MAJ, MC PRINCIPAL INVESTIGATOR(S): William P. Wiesmann, MAJ, MC						
ASSOCIATE INVESTIGATOR(S):		·		· · · · · · · · · · · · · · · · · · ·		
FACILITY: KRAYE/WRAIR	DEPT/Sic: Dept	of Medic	ine/Nephrolog	gy Service		
ACCEPTE ATTYE PEDCASE COST:	ACCUMENTIVE CONTRACT	Cost:	ACCUMULATIVE S	UPPLY COST:		
FY-83 PEDCASE: CONTRACT C	OST: SUPPLY COST:	DATE OF AMMUAL P	COMETTEE APPROPRIESS REPORT	VAL 0F FEB 2 5 1993		
STUDY OBJECTIVE: To assess the contribution of Cholinergic receptor activity to the pathogensis of hemolytic anemia in uremic patients.						
TECHNICAL APPROACH: The technical approach is as described in the original protocol to include analysis of deoxynucleosides as indicators of cholinergic activity and there rate of appearance in renal disease and there relation to RBC function.						
PROSRESS During FY-82: The assays for cholinergic receptor activity and cGMP have been refined and more fully developed.						
Huraen of Subjects Studied:	• .					
FY-82: None Tot	AL (TO DATE): 15	Befor	E CONPLETION OF	STUDY: 60		
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(1F HOME SO STATE): None						
Coxorusions: Data is insufficient						

Publications or Asstracts. FY-82: 1) Abnormal Deoxy Adenosine Metabolism in Uremic Erythrocytes. W. P. Weismann and H. K. Webster. To be presented 14th Annual Meeting The American Society of Nephrology Washington, DC Nov. 21-24, 1981. 2) Calcium stimulated cGMP Formation in Human RBC Treated with Cholinergic Agonists. L. Tang and W. P. Wiesmann. To be presented Annual Meeting, The American Society of Hematology San Antonio, Texas, December 5-8, 1981.

DATE: 7 Oct 82 Nox UNIT N	o.:1138	STATUS: INTERIMENT	Firm		
STARTILLS DATE: 15 Jan 82	STARTING DATE: 15 Jan 82 DATE OF COMPLETION: Jan 85				
Key Nords: glomerulonephritis, cytotoxic agents, bolus steroids					
TITLE CF PROJECTSteroid and Glomerulonephritis	Immunosuppressive D	rug Therapy in Id	iopathic Crescentic		
PRINCIPAL INVESTIGATOR(S): Jac	k Moore, Jr. MD, MAJ	, MC			
ASSOCIATE INVESTIGATOR(S): NO	NE				
FACILITY: NRANC XX	DEPT/SVC: Medicin	e/ Nephrology			
Accumulative PEDCASE Cost:	ACCUMULATIVE CONTRACT CO	0			
FY-83 PEDCASE: CONTRACT COS	T: SUPPLY COST:	ATE OF COMMITTEE APPR NAUAL PROSRESS REPORT	OVAL 0F FEB 2.5 1983		
Both groups receive oral cor	e in a randomized tr ticosteroids	ial in patients w			
TECHNICAL APPROACH: After bit to cause this disorder, Pts q month for 6 months, or iv will program be appreciately 12.	opsy proof of cresce will be randomly ass methylprednisolone e	ntic GN, and excling igned to receive ach month for 6 mg	usion of diseases known either i gram iv ctx onths. Repeat biopsy		
no patients studied-	protocol approved 1	5 Jan 82			
Минявая от Визивсть Втиртер:					
FY-82: 0 TOTAL	(TO DATE): 0	BEFORE COMPLETION OF	F STUDY: 20		
Serious/Unexpected Side Effects in Subjects Participating in Project(if none so state): no serious effects since no patients studied					
Conclusions: No patients streeruitment, therefore this	udied- nature of the is a collaborative p	disease precludes rotocol with the I	s rapid patient NIH		
		·			
PUBLICATIONS OR ASSTRACTS. FY-8	12:				
none					

DATE: 7 Oct 82 Now UNIT N	o.: 1139 Sta	ATUS: INTERIM XX FINAL
STARTING DATE: Jan 82	DATE OF COMP	LETION: Jan 85
KEY NORDS: erythrocytosis;	transplant; erythropoi	ietin
TITLE OF PROJECT: Erythrocy	tosis in Renal Allograf	ft Receipients
•	•	
		MO 1 MO 1 MO MAI MC
		, MC Jack Moore, Jr. MD, MAJ, MC
	1	PT, MC Jimmy A Light. MD, COL, MC
FACILITY: WAYE	DEPT/Syc: Medicine/	
Accumulative MEDCASE Cost: 0	ACCUMULATIVE CONTRACT COST:	ACCUMULATIVE SUPPLY COST:
FY-83 FEDCASE: CONTRACT COS 0 1000 00		E OF COMMETTEE APPROVAL OF DAL PROGRESS REPORT FEB 2 5 1983
thropoietin. Then, allogra Paggass William Ey-82.3 pation attents were demonstrated atient did not have an erg	aft biopsies are done, ents were studied- none two have erythropoieti	: showed evidence of allogra ft reject in emanting from their native kidneys
Murber of Subjects Studied: 3 FY-82: 3 Total	(TO DATE): 3 B	BEFORE COMPLETION OF STUDY: 10
SERIOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPATING I	n Pagiscr(is nows ag crare).
		•
	<u>d effects have occurred</u> ee patients. ervthropoi	etin appears to emanate from the
ive kidney, not from the a	allograft. Additionally ests that the native ki	there appears to be no evidence of idneys are responsible for the
PUBLICATIONS OR ABSTRACTS, FY-5	₮:	

DATE:11/17/82 Now Unit No	o.: 1140	STATUS: INTERIM X FIRM			
STARTILE DATE: June 1982	DATE OF	F Corpustion: Undetermined			
Kev Capas; Acute Renal Failure, Vitamin D, Calcium and Phosphate Time of Project: "The Role of Vitamin D in Calcium and Phosphate Imbalance in Acute Renal Failure"					
PRINCIPAL INVESTIGATOR(S): Clifford Ferguson, MD, MAJ, MC, Fellow Nephrology Svc Daniel A. Nash, Jr., MD, COL, MC, Chief Nephrology Service					
		, MAJ, MC, Asst., Chief Nephrology Service			
FACILITY: KRAYS	DEPT/SVC:				
ACCUPULATIVE NEDCASE COST:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:			
FY-83 PEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF AMMUAL PROGRESS REPORT FEB 2.5 1982			
STUDY OBJECTIVE: To determine the relationship of Vitamin-D on the calcium and phosphate imbalances previously noted to occur in					
patients with acute renal failure renal failure will be selected TECHNICAL APPROACH: Patients with acute renal failure will be selected and interval measurements of 125,2425, and 25 hydroxy Vitamin-D will be made in measurements correlated with serum calcium,					
PROSESSATION PLEASE at a thy	roid measuremen	its.			
HUMBER OF SUBJECTS STUDIED:					
FY-82: O TOTAL	(TO DATE): 0	BEFORE CONSUMITION OF STUDY: 12			
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE): NONE					
CONCLUSIONS:					
	NONE				
PUBLICATIONS OR ASSTRACTS. FY-	Ω :	•			

NONE

Date: 11/17/82 Now Ever No.: 1141	STATUS: INTERIN X FIGUR
STARTICE DATE: July 1982 Date of	F COPLETICH: June 1983
Key Coms: Potassium, Dialysate Glucose	
T	ssium Removal By Hemodialysis"
PRINCIPAL INVESTIGATOR(S): Daniel A. Nash, Jr.,	MD, COL, MC, Chief, Nephrology Service
ASSOCIATE INVESTIGATOR(S): FACILITY: KRAYC DEPT/Syc: Dept	Medicine/Nephrology Service
ACCUMULATIVE PEOCASE COST: ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:
FY-83 PEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FETTE 5-1903
STUDY OBJECTIVE: To determine the influence oncentration on the rate of potassic	ce of dialysate glucose um removal during
Standard hemodialysis. TECHNICL APPROACH: Direct measurement of standard hemodialysis utilizing either	dialysate effluent during er a low or high dialysate
PROSESS DERING FY-82: Five patients have be utilizing high and low glucose dialy	een adequately evaluated sate with measured
DOTAGRIUM LORSES. MUMBER OF SUBJECTS STUDIED:	
FY-82: 7 TOTAL (TO DATE): 7	BEFORE COMPLETION OF STUDY: 20
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPA	TING IN PROJECT(IF NOWE SO STATE):
Coxo us tons:	•
Initial observations would diabetic patients that dialysate gluminimal effect on the rate of potass standard concentration of dialysate clinically.	cose concentration has ium removal in the
	mitted to the Clinical

Abstract submitted to the Clinical Dialysis and Transplantation Forum and accepted for presentation at their Annual National Meeting. The abstract will be expanded into a formal paper addressing the details and the data that supported the abstract, and will be published in the proceedings of the Clinical Dialysis and Transplantation Forum.

DATE: 3.JAN83	HORK UNIT N	0.: #1217		STATUS:	INTERIM X	Firal
START 1:3 DATE: 1	5 DEC 198	0	DATE OF	COMPLETION	: N/A	
KEY WORDS: N/A						
Time of Project: Arrhythmias			∞darone	for T	herapy of	Cardiac
PRINCIPAL INVESTI		Villiam J.				
ASSOCIATE INVESTI	GATOR(S): J	ames E. D.				
FACILITY: WRANC		DEPT/SVC	: Card	liology		
Accumulative MEDC	ASE Cost:	ACCUMULATIVE -0-	CONTRACT C	OST: A	CCUMULATIVE S	UPPLY COST:
FY-83 IEDCASE:	CONTRACT COS	T: Supply Cos		Date of Co Annual Pro	MITTEE APPRO GRESS REPORT	val Of N/A
STUDY OBJECTIVE:	No Chan	ige				
TECHNICAL APPROAC	н: No Chan	ıge		 , , , , , , , , , , , , , , , , , 	·	
PROGRESS DURING F	<u>Y-82</u> :			·		
	N/A					
HUMBER OF SUBJECTS	STUDIED:					
FY-82 <u>: 19</u>	TOTAL	(TO DATE):	19	_ Before (COMPLETION OF	STUDY: N/A
SERIOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PA	RTICIPATI	es in Proje	ECT(IF NONE SO	STATE):
	tached me	emo ·	····	·		
CONCLUSIONS:						
None	as yet					
	· · · · · · · · · · · · · · · · · · ·					
PUBLICATIONS OR A	STRACTS, FY-8	2:	,	· · · · · · · · · · · · · · · · · · ·		

None

For use of this form, see AR 340-15, the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-MC

Annual Progress Report FY 82, Clinical Investigation Program Work Unit #1217 "Evaluation of Amiodarone-<u>for Cardiac Arrhythmias</u>

XXXX

THRU: C, CIS

Dir, CCU

10 JAN 83

LTC OETGEN/rj/63836

TO: HODA

SGRD-HR

Wash., D.C. 20314

- 1. In accordance with AR 40-7 the following data are submitted:
- a. Specific study evaluation of amiodarone for the therapy of cardiac arrhythmias - WRAMC Work Unit #1217; IND #17858, Principal Investigator: William J. Oetgen, MD, LTC, MC; James E. Davia, MD, COL, MC.
 - b. Location: Walter Reed Army Medical Center
 - c. Number of subjects: 19 (see below)
 - d. Narrative of progress of patient (see below)
 - (1) Della Kearney see 1981 report
 - (2) Charles Guthrie see 1981 report
- (3) Allan Barnabei see 1981 report. Patient continues to do well, no side effects reported. Arrhythmias controlled.
- (4) William Hoffman see 1981 report(5) Henry Robinson see 1981 report. Patient has been discontinued because of development of pulmonary fibrosis probably secondary to amiodarone therapy.
- (6) Curtis Clemmons see 1981 report. Patient continues to do well, no side effects reported. Arrhythmias controlled.
 - (7) Linda Hedley see 1981 report
- (8) Hans Heckes see 1981 report. No symptoms. Amiodarone was discontinued on 9 March 1982 because of the clinical opinion that the arrhythmias were associated with acute myocarditis and that the likelihood of arrhythmias now are small. The patient will be see in follow-up.
- (9) Leana Fisher 539-44-8314. Amiodarone discontinued on 27 September 1981. Ventricular tachycardia recurred February 1982; amiodarone was restarted for two weeks and was discontinued on 10 March 1982 because of photophobia.
- (10) William Liverman see previous report. The patient was discontinued on 25 April 1982 because of fatigue, malaise, nystagmus, poor coordination and failure to control arrhythmias. He is currently doing well on another experimental antiarrhythmic.
- (11) James McMahon 036-07-6469 72 year old male with aortic stenosis and ventricular tachycardia. The patient was started on amiodarone on 17 April 1982. He underwent aortic valve replacement on 19 April 1982 and continues to do well on therapy.
- (12) Clark Norman 005-32-1986 45 year old male with coronary artery disease and ventricular tachycardia. Following administration of amiodarone, the patient had three episodes of ventricular tachycardia on successive days. He has been discontinued because it was felt that the amiodarone facilitated a ventricular tachycardia.

HSHL-MC (10JAN83)

SUBJECT: Annual Progress Report FY 82, Clinical Investigation Program Work Unit #1217 "Evaluation of Amiodarone

for Cardiac Arrhythmias"

(13) Charles Collins - 20-218-24-5046. A 46 year old male with coronary artery disease, post myocardial infarction in 1975 with recurrent symptomatic ventricular tachycardia. The patient has been refractory to conventional antiarrhythmics and to flecanide. Amiodarone was begun on 3 November 1982. The patient continues to do well.

(14) Herbert Lawrence 438-50-5752. A 45 year old male with ischemic cardiomyopathy, and ventricular tachycardia. The patient was intolerant to conventional antiarrhythmics. He was started on amiodarone on 16 June 1981 for control of his arrhythmias, however, he had a stroke and died on 1 January 1983. It is not felt to be secondary to amiodarone therapy.

(15) Masters, William - 361-03-0167. A 63 year old white male had a large anteroseptal infarction with refractory ventricular tachycardia. He died of ventricular fibrillation 24 December 1981, five days after addition of amiodarone therapy.

(16) Leonard, Grace - 061-12-1286, a 67 year old female with ventricular tachycardia, post myocardial infarction. Started on Amiodarone 10 November 1982, because of nausea and anorexia, the dose

has been decreased to 400mg a day. The patient is doing well.

(17) Shomion, Arthur - 257-60-2229, A 70 year old male with ischemic cardiomyopathy, and ventricular tachycardia. Amiodarone started 15 November 1982. The patient continues to do well.

(18) Hughlett, Richard - 215-09-2531: A 67 year old male with coronary artery disease and ventricular tachycardia. Began amiodarone 10 November 1982 and the patient continues to do well.

(19) Brewster, James: A 54 year old white male with coronary artery disease, ventricular tachycardia. Amiodarone started 15 November 1982. The patient is doing well.

WILLIAM J. OETGEN, MD

LTC, MC

DATE: 3 JAN 83 HORK UNIT No.: #1218 STATUS: INTERIM X FIRST						
START 1:25 DATE: 15 NOV 82 DATE OF	F COMPLETION: Ongoing					
KEY VORUS:						
Time of Project: Cardiac Manifestations	of Polymyositis					
PRINCIPAL INVESTIGATOR(s): William J. Oeto	gen, MD					
ASSOCIATE INVESTIGATOR(S): James E. Davia	, MD					
FACILITY: WRANC DEPT/Svc: Care	diology/WRAMC					
ACCUMULATIVE NEDCASE COST: ACCUMULATIVE CONTRACT	Cost: Accumulative Supply Cost: \$345.00 (Routine patient care)					
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT N/A					
STUDY OBJECTIVE:						
No Change	<u> </u>					
TECHNICAL APPROACH:						
No Change						
PROGRESS DURING FY-82:						
No patients were admitted	to study in FY-1982					
Mumber of Subjects Studied:						
FY-82: 0 TOTAL (TO DATE): 5	BEFORE COMPLETION OF STUDY:					
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPAT	TING IN PROJECT(IF HONE SO STATE):					
None .						
CONCLUSIONS:						
None						
PUBLICATIONS OF ABSTRACTS, FY-82:						
FUBLICATIONS OF UBSIKACIS: FITOLI						

None

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-MC

Clinical Investigation Program

TO Clinical Investigation FROM C, Cardiology Svc

CMT 1

COL DAVIA/rj/63836

DATE 26 NOV 82

- 1. Clinical investigation program, work unit #1220, Efficacy of Nifedipine in the Management of Angina Pectoris was initiated by MAJ Fayaz A. Shawl, MC.
- 2. The project was terminated as of 30 June 1982 for two reasons:
- a) The drug under investigation, nifedipine, was released on the commercial market several months ago.
 - b) MAJ Shawl became a civilian on 30 June 1982.

JAMES E. DAVIA, MD

CÓL, MC

Chief, Cardiology Service

DATE: 7 Dec 82 Mark Unit No.: 1221	STATUS: INTERIN XX FIRM
STARTING DATE: 1 Aug 81 DATE OF	Conteriou: Unknown
KEY LORDS: Pacemaker TIME OF PROJECT: Clinical Evaluation of and Advanced Functioning Pacemaker.	AV Sequential Pacemaker
PRINCIPAL INVESTIGATOR(S):Dr. James E. Davia	, COL MC
ASSOCIATE INVESTIGATOR(S):Dr. Russ Zatzchuck	. COL MC
FACILITY: IRANC DEPT/S/C: Cards	ology, and Thoriacic Surgery
ACCUMULATIVE PEDCASE COST: ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1003
STUDY OBJECTIVE: To test clinically an AV an advanced function pacemaker. TECHNICAL APPROACH: Implantation and foll	
PROSRESS DURING FY-82: Five AV sequential p	acemakers implanted.
Murses of Subjects Studied:	
FY-82: TOTAL (TO DATE): 5	BEFORE COMPLETION OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPAT None	ING IN PROJECT(IF NONE SO STATE):
CONCLUSIONS: The A-V sequential pacema	ker has functioned normally
PUBLICATIONS OR ABSTRACTS, FY-82:	

DATE: 11 NOV 1982 LAST	No.: 1223	STATUS: INTER	in Fran	X
STARTING DATE: 18 Jan 19	82 DATE OF	CONNETTICIL: 1	5 May 1982	
	lar Screening Evalua			
TITLE CF PROJECT: A Piglt For Car	Multi-Stage Cardiov	ascular Scree in Asymptom	ning Evaluation	on to Test ity Army
Personn	el Over the Age Fort	у.		
PRINCIPAL INVESTIGATOR(S):	Jerel M. Zoltick,			mes Vogel, PhD
ASSOCIATE INVESTIGATOR(S):	James Davia, M.D.	; Julius Bedyn	ek, M.D. Phb	
FACILITY: RATE/Dunham He		icine/ Cardiol	.ogy	
Accurative rescar Cost:	ACCUMULATIVE CONTRACT none f rom HS	Cost: Accumu	LATIVE SUPPLY COS	for nuclear studie
FY-83 PEDCASE: CONTRACT C	OST: SUPPLY COST:	DATE OF COMMETT KINUAL PROGRESS	EE APPROVAL DE REPORT	\$2000 for overting from Hosp funds.
STUDY OSJECTIVE:				iid q.
To dete	ermine extent of Cor	onary artery o	lisease in an	asymptomatic
TECHNICAL APPROACH: To ide	ntify cardioarte	ry disease	in asymptoma	itic males
over the age of 40, active duty militar	a dardiovascula	r screen was	s performed n the attach	on 249 ned sheet.)
	inical testing perf			
. Nu	clear Testing 1 Mar	ch-30 April 19	982	
Hursen of Subjects Studied:	SPONSTY ROGINGLADOV.	I May-Zondy 1.		
FY-82: 249 Tot	AL (TO DATE): 249	BEFORE CONPL	בינטא פר אנטוע <u>:</u>	•
SERIOUS/UNEXPECTED SIDE EFFE	CTS III SUBJECTS PARTICIPA	ring in Project(i	F NOVE SO STATE):	•
Concrustons:				
Using a multitude of t 23 individuals. 13 har required CABG surgery during any of the test	d critical coronary and 1 requiring angi	artery diseas oplasty. The	re were no com	mplications
	Cardiovascular Scree Artery Disease in As	symptomatic Ma	les over the a	age of Forty.
	Approved for publication Am	tion: Am Jour Coll of Cardi	n of Card, Mar ology, March	rch, 1982. 1982.

Note: Exact funding Requirements came from USARIEM, Natick, Mass for the initial study at Carlisle Barracks, Pa. The funding for the Nuclear studies, coronary angiography, and coronary artery bypass (the later two were not part of the study, but were recommended by cardiologists and thoracic surgeons not part of the research team) came from general expenses from the respective departments. The only added expense was overtime, approx \$2000. which came from general hospital funds as per General Mendez.

The following coronary risks were evaluated on the population: cardiovascular history and exam, family history, tobacco history, ECG, fasting blood sugar, cholesterol, cholesterol- HDL ratio, triglycerides, percent body fat, calculation of Framingham risks index. All subjects had normal treadmill tests, cardiokymography and determination of maximal oxygen consumption. Patients with an abnormal treadmill test, i.e., greater than 1 mm depression and/or abnormal cardiokymography underwent further testing: fluoroscopy, exercise value study and reaionuclide ventriculography. Patients with abnormal results were referred to an outside Army cardiologist (not part of the study) for recommendations for follow-up.

* - 			
DATE: 9 NOV82 HORK UNIT	b.: 1224	STATUS: INTERIM XX FIRM	·
STARTING DATE: January	1982 DATE 0	F COMPLETION: June 1982	_
KEY WORDS:			_
TITLE CF PROJECT: PULMONA PROGRESSIVE SYSTEMI	RY VASOSPASM IN C SCLEROSIS: PI TO NIFEDIP	RAYNAUD'S DISEASE AND REVALENCE AND RESPONSE INE	~
PRINCIPAL INVESTIGATOR(S):	John W. Shuck, 1	MD, MAJ, MC	
ASSOCIATE INVESTIGATOR(S):	William J. Oetg	en, MD, LTC MC	
FACILITY: WRAYE	DEPT/Syc: Car	diology	_
ACCUMULATIVE MEDICASE COST:	Accumulative Contract O	COST: ACCUMULATIVE SUPPLY COST: 0	~
FY-83 FEDCASE: CONTRACT COS	T: SUPPLY COST:	Date of Committee Approval Of Annual Progress Report FEB 25 198	3
STUDY OBJECTIVE: To evalu vasodilator Nifedip		pulmonary hypertension a	ñd
TECHNICAL APPROACH: Clini and right heart cat		asive evaluation patients	
PROSRESS DURING FY-82: Four	patients studie	d to date, FY-82.	-
MUMBER OF SUBJECTS STUDIED:		(proje	
FY-82: 4 TOTAL	(TO DATE): 4	BEFORE COMPLETION OF STUDY: 16 a	dditional -
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPAT	TING IN PROJECT(IF NONE SO STATE):	-
- 	r patients four	d with pulmonary hyperten	sion.
Two of these two pat with Nifedipine; the	ients decreased two remaining	pulmonary vascular resis patients without pulmonar hypertension with cold pr	tance y hyper-
PUBLICATIONS OR ABSTRACTS. FY-	32:	· · · · · · · · · · · · · · · · · · ·	_

NONE

HSHL-MC (27 AUG 82)

SUBJECT: WRAMC WU# 1225: "Intracoronary Thrombolysis With Streptokinase"

TO: Clinical Investigation Service FROM: Dir, CCU DATE: 2 DEC 82 CMT2 LTC OETGEN/rj/63836

- 1. Soon after this protocol was approved, the FDA approved streptokinase for intracoronary administration on a non-protocol basis.
- 2. Several recent papers have been published which clearly document the efficacy of intracoronary streptokinase in the setting of an acute M.I.
 - 3. Publication of the results of this study would be unlikely.
 - 4. No patients have been entered in this study to date.
 - 5. Request that this study be terminated and that HSC (see attached DF) be informed of this termination.

WILLIAM J. OETGEN, MD

LTC, MC

DATE:9 NOV 82 HOPK UNIT No.: 1226	STATUS: INTERIM XX FINAL
STARTING DATE: Feb 1982 DATE OF CO	MELETION: Feb 1983 (est.)
Key Horas:	
TITLE CF PROJECT: ELECTRICAL CARDIOVERSION DIGITALIS.	N IN PATIENTS TAKING
PRINCIPAL INVESTIGATOR(S): John W. Shuck, MD,	
Associate Investigator(s): William J. Oetgen,	MD, LTC MC
FACILITY: WRANC DEPT/Svc: Card:	iology
ACCUMULATIVE PEDCASE COST: ACCUMULATIVE CONTRACT COST	ST: ACCUMULATIVE SUPPLY COST: O
FY-83 MEDCASE: CONTRACT COST: SUPPLY COST: A	ATE OF COMMITTEE APPROVAL OF HUMAL PROGRESS REPORT FEB 2 5 1983
STUDY OSJECTIVE: Determine the incidence during cardioversion in patients on	
TECHNICAL APPROACH: Determine blood digital: cardioversion monitoring arrhythmias	is levels at time of
PROGRESS DURING FY-82: None	version
Number of Subjects Studied:	
FY-82: 0 TOTAL (TO DATE): 0	BEFORE COMPLETION OF STUDY: 30
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING	IN PROJECT(IF HOME SO STATE); None
Conclusions:	
·	
Publications or Abstracts, FY-82:	

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-MC

Flecanide Study Protocol R-818-037-WRAMC WU #1227

to C, CIS

FROM Dir, CCU

DATE 9 FEB 83

LTC OETGEN/rj/63836

RU.S. GOVERNMENT PRINTING OFFICE: 1982-372-711

1. Please see attached letter terminating entry into WU \$1227 and cancelling protocol.

- 2. One patient (Grace C. Leonard) was entered into study by emergency approval prior to HSC approval (which has not yet been received). This patient had one episode of ventricular tachycardia on protocol, and the code was broken, indicating that she had been receiving placebo.
- 3. Because R-818-028 (Open label Flecanide protocol) was closed to admission, the patient was started on Amiodarone (WU #1217) and has done well.
- 4. Please terminate WU #1227 and inform HSC of this termination.

WILLIAM J. OETGEN, ME

LTC, MC

For use of this form, see AR 340-15; the proponent ag

REFERENCE OR OFFICE SYMBOL

SUBJECT WRAMC WU #1228

A Placebo Controlled - Double Blind Evaluation of

Oral Amrinon .. HSHL-MC

DATE 1 DEC 82

CMT 1

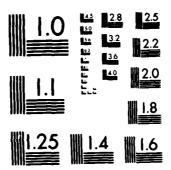
TO C, Clinical Investigation W.J. Oetgen, MD LTC OETGEN/rj/63836

- 1. The sponsoring pharmaceutical company terminated entry of patients into this study, prior to final approval of WRAMC protocol #1228.
- 2. No patients were admitted to this WRAMC protocol. Several patients were referred from WRAMC to the Washington VA Hospital where they entered this study under a VA protocol.
- 3. Request that this study be terminated.

WILLIAM J. OETGEN, MO

LTC, MC

AD-A129 2	42 ANNU ARMY	JAL PROG MEDICA	RESS RE	PORT F	Y-82 VO INGTON	LUME I(DC T M	U) WAL1 BOEHM	TER REED 1982)	2/4	
UNCLASSIF	IED						F	/G 6/5	. N	L .	



MICROCOPY RESOLUTION TEST CHART
NATIONAL BUREAU OF STANDARDS-1963-A

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-MC

Flecainide Actetate Protocol R818-028-WU #1229

DATE

CMT 1

C, CIS

Dir, CCU

9 FEB 83 LTC OETGEN/rj/63836

- 1. Please see attached letter from Riker Laboratories, Inc.
- 2. Four patients were admitted to this protocol. Two patients had recurrent ventricular tachycardia while taking flecainide, and they were taken off the drug.

Two patients (Leana Fischer and William Liverman) have continued to take the drug and are doing well.

- 3. As per attached letter, no new patients will be admitted to this drug protocol until enrollment is resumed by drug company.
- 4. The attached abstract was accepted for poster presentation at the American Federation for Clinical Research meeting in Washington, D.C. April 1983.
- 5. A full draft of this report will follow.
- 6. Please confirm that full HSC and SGO approval has been granted for WU #1229; we do not have written documentation of this fact in our file although it has been acknowledged verbally by Mrs. Ervin.

WILLIAM J. OFTGE

LTC, MC

DATE: 250ct82	HORK LINET N	o.: 1311	STATUS	: INTERIM X	Final
STARTING DATE:	29 March 1	974 DATE	OF COMPLET	101: August	1982
KEY VORDS: Res	in/Thyroid	Storm			
TITLE OF PROJECT:	Treatmen	t of Thyroid Stor	m with	Anion Exchang	e Resin
			•		
PRINCIPAL INVESTI	gator(s):	Kenneth D. Burmar	LTC,	мс	
ASSOCIATE INVESTI	GATOR(S): L	eonard Wartofsky,	COL, M	С	
FACILITY: WATE		DEPT/Svc: Der	t of Me	d/DCI/KMU	
ACCURREATIVE PEDC	ASE Cost:	ACCUMULATIVE CONTRAC		ACCUMULATIVE S	UPPLY COST:
FY-83 PEDCASE:		· · · · · · · · · · · · · · · · · · ·	FINNUAL	COMMITTEE APPROPRIES REPORT	## 5 5 120 3
anion exchange hormones TECHNICAL APPROACT is perculated and a column of PROGRESS DURING FOR this protoc threatening citizens of Subjects	e resin in H: Venous of through the containing Y-82: It sh col. However the rumstance s Studied:	thyroid hormones a patient require atherter is placed is catherter with resin is interposed by the catherter with resin is interposed by the catherter with resin is interposed by the catherter with the catherter with resin is interposed by the catherter with t	ng imme ed in th n a veno sed betw n that n n storm to have	e patient, pe us to venous een the venou o patient has is a potentia this protocol	ripheral blood anastromasosis channels and been entered ally life on record in
FY-82 <u>:</u>	TOTAL	(TO DATE):	BEFO	RE COMPLETION OF	Sπυογ: 1-5
SER LOUS/UNEXPECTED	SIDE EFFECTS	S IN SUBJECTS PARTICIP	ATING IN P	ROJECT(IF MONE S	O STATE):
CONCLUSIONS:	None yet.				
PUBLICATIONS OR AS	SSTRACTS, FY-8	32: None yte.			•
Technical Apout the thyr			his ve	nous channe	l will filter

Progress During FY-82 (continued): a continuing fashion to be available in case such a patient did come in the hospital.

Dare: 8 Sep 82	Post Unit Ro.: 1341-82	Sminis	: Jerenia	*xxx					
STANTING DATE: DATE OF COMMETTION: 2 yrs									
Yes Users FSH.	Testosterone, HCG	Livers of the second		· O · · · · · · · · · · · · · · · · · ·					
	Effect of FSH (Pergona inoma or Other HCG-sec			ne in Men					
	Non(s): Robert A. Vigers								
ASSOCIATE TIMESTIC	Avon(s): David Bloom, M.D.	•		e partie in constitution (s. e. d. s. partie colores de constitution de l'acceptant de constitution de l'acceptant de constitution de l'acceptant de constitution de l'acceptant de l'acce					
FACILITY: KRANC	The state of the s		lic Muit	Miles and the conference of th					
Accumularive 1200AS	S Cost: Accumbiative Co.								
FY-85 PERCASE: 0	Contract Cost: Supply Cost: \$3,760	Pare of Englag	Committee Apri Progress Remor	ROVAL OF T. JEB 2.5 1933					
	elucidate the mechani in men with HCG-secreti		testostero	ie is inapprop	ciatoly				
	A short BGG test to been seven days of FSH 22			n ECG-secreting	, tumo es				
	82: The protocol has no the Serono Co. has not			e Pergonal what	ch is to				
Homsela of Suburiers	Studied:	······································	e interes in a manage en						
FY 82: 0	TOTAL (TO DATE):	0 Been	RE COMPLETION (of Shoy: 10					
Serious/Unexpected Not applicable	Sing Envents in Substitute the v		•	\$3 \$7A.2):					
Conclusions: The	study should begin bef	ore the end	of the cal-	callar year.					
	-								
	•,								
PUBLICATIONS OR ABS	телств. FY-82: о		man						

Copy available to DTIC does not permit fully legible reproduction.

DATE: 8 Oct 82 How Unit No.: 1354	STATUS: INTERIM KANA
START INS DATE: 3 Nov 1976	DATE OF COMPLETION: 30 Sept 1983
KEY 10005: Testosterone, Estradiol, B	inding Globulin
TITLE CF PROJECT: Purification of Test	osterone Estradiol Binding Globulin
	•
PRINCIPAL INVESTIGATOR(S): Robert A. Vi	gersky, M.D.
ASSOCIATE INVESTIGATOR(S):	
FACILITY: KRAYC DEPT/SVC	: Kyle Metabolic Unit
Accumumative MEDCASE Cost: Accumumative None None	CONTRACT COST: ACCUMULATIVE SUPPLY COST: \$4,114.83
FY-83 FEDCASE: CONTRACT COST: SUPPLY COS \$500 \$4,000	
Study Osjective: See Attached	
TECHNICAL APPROACH:	
See Attached	
PROGRESS DURING FY-82:	
See Attached	·
Humsen of Subjects Studied:	
FY-82: Not Appl. TOTAL (TO DATE):	BEFORE COMPLETION OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PA Not Applicable	ARTICIPATING IN PROJECT(IF NONE SO STATE):
CONCLUSIONS: Purification of TEBG has is to use this to construct a radioi	been accomplished and the present air
Publications on Abstracts, FY-82: None	

Work Unit No: 1354

Study Objective: To purify, characterize, and develop a radioimmunoassay for TEBG. This binding protein controls availability of sex steroids to breast, skin and prostate.

Technical Approach: Sequential use of concanavalin A in affinity chromatography and preparative polyacrylamide gel electrophoresis. Quantitative analysis of the progress of purification by the use of analytical polyacrylamide gel electrophoresis and dextracharcoal assay measuring total binding capacity.

Progress During FY82: We have used successfully the strategy of sequential purification to purify TEBG to homogeneity. The last few months have been spent by using this strategy to accumulate sufficient quantities of the purified proteins to inject into rabbits for the formation of antibodies and for iodination.

DATE: 210ct82	HORK UNIT NO	: 1358	STATUS	INTERIM	_X	Final	
STARTING DATE:		Date	OF COMPLET	ION:			
Key Words: Obesi	ty/Fasting	/T3 Receptors					
Time of Project: Cells	The Effect	of Obesity and	Fasting	on T3 Rec	epto	rs in Mor	nonuclear
PRINCIPAL INVESTIG	ATOR(s): Ke	nneth D. Burman	, LTC, MC				
ASSOCIATE INVESTIG	Lec	onard Wartofsky Vllis Kosler	, COL, MC	, Keith L	atha	m, Ph. D.	•
FACILITY: WRANC			ept of Me	d/ Endo/K	JMU		
ACCUMULATIVE PEDCA	SE Cost:	ACCUMULATIVE CONTRA	ct Cost:	ACCUMULAT	ive Su	PPLY COST:	
FY-83 I'EDCASE:	CONTRACT COST	: Supply Cost:	DATE OF ANNUAL	COMMITTEE PROGRESS RE	PPROV	1 0 2 5	1983
action and rec both in the fe TECHNICAL APPROACH approximately gradiant is on PROGRESS DURING FY	eptor bidn: d and fast; A T3 so; 14-18 mls o tained. T1 -82: T3 rec ity and pro hey are inc	lubilized recept of blood are obt ne mononuclear o ceptors are util bbably unchanged	tor assay tained in cells are izing un:	has been a green obtained solubiliz	deve top t	se patient eloped in tube, fic this mann echniques	nts, n which coll-hypaque ner and s are
FY-82: 20	TOTAL (TO DATE): 20	BEFOR	E COMPLETIO	אס אכ	Study:	30
SERIOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PARTICI	PATING IN P	OUECT(IF NO	ONE SO	STATE):	 .
probably decr	ease during	vary depending of fasting and using solubility	se unsolu	bilized t	naly: ecnh	sis, but iques and	they d
Publications or Ab Sciences, 1981		: JCEM, volume	51, pag to Journ	e 106, 19 al of CLi	80 an	nd Life l Endocri	 inology

Work Unit # 1358

Technical Approach Cont'd:

extracted with ammonium sulfate and the solubilized preparation of thyroid hormone receptor is used to determine T3 and T4 binding. Utilizing this technique we have studied approximately 20-25 patients in obesity who are obese and fasting and have published and have found that T3 receptors are unchanged during obesity and may increase during fasting. However, an alternative method of performing this technique is now being investigated in our -aboratory which would involve isolation of the mononuclear cells on ficoll-hypaque gradiant but not to solubilize them but just put the white cells into binding tubes. This assay gives different results than earlier noted and that we are in the process of repeating these studies on a separate group of 20 obese patients. It should be noted that this assay requires approximately 40 mls of blood where as the earlier assay only required 20 mls of blood. In general, our approach will be to perform the assay on days 4 and 5 of the fed period and days 6 and 7 of the fasting period.

DATE: 12 Oct82 HORK UNIT N	o.: 1368 Sr	ATUS: INTERIM X FIRM
STARTING DATE: 26 April 1977 DATE OF COMPLETION: 30 September 1983		
Key kords: Phosphate, Vitamin D Metabolism		
Time CF PROJECT: Effect of Dietary Phosphate on Serum Levels of Vitamin D Metabolites in Hypoparathyroidism		
PRINCIPAL INVESTIGATOR(s): H. Linton Wray, COL, MC		
ASSOCIATE INVESTIGATOR(s): Joseph Bruton, Ph.D., Ira Mehlman, LTC, MC		
FACILITY: WRATE DEPT/Svc: Kyle Metabolic Unit		
ACCUMULATIVE MEDIASS COST: \$12,662	ACCUMBLATIVE CONTRACT COST \$4,553	: ACCUMULATIVE SUPPLY COST: \$85,812
	T: SUPPLY COST: DAT \$21,000 PANN	E OF COMMITTEE APPROVAL OF UAL PROGRESS REPORT FEB 2.5 1933
STUDY OBJECTIVE: See Attached		
TECHNICAL APPROACH: See Attached		
PROGRESS DURING FY-82:		
See Attached		
Murbea of Subjects Studied:		
FY-82: 0 TOTAL	(TO DATE): 8	BEFORE COMPLETION OF STUDY: 10
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE): None		
CONCLUSIONS: Deferred		

PUBLICATIONS OR ABSTRACTS. FY-82:

Wray HL, Mehlman I, Sheldon GM, Butler VM, Dawson E, Bruton J. Effect of Dietary Phosphorus Restriction and Magnesium/Aluminum-Containing Antacid Treatment on Serum 1,25(OH),D in Pseudohypoparathyroidism in Vitamin D-Chemical, Biochemical and Clinical Efidocrinology of Calcium Metabolism, Eds Norman AW, Schaefer K, Herrath DV, Grigoleit H-G, pp. 665-667, Walter DeGruyter Publishing Company, New York, 1982.

Study Objective: To determine if serum levels of 25-OH-D (25 hydroxy-vitamin D), 24,2(OH)₂D (24, 25-dihydrodxyvitamin D) and 1,25-(OH)₂-D (1,25-dihydroxy vitamin D) are changed by short-term manipulation of dietary phosphate intake in hypoparathyroid patients.

Technical Approach: The 15 day protocol consists of 2 days on normal phosphate intake (1.0 g of phosphorus), 10 days on low phosphate intake (0.5 g of phosphorus) and 3 days on high phosphate intake (1.5 g phosphorus). During the period of phosphate restriction, phosphate-binding antacids will be given. Serum inorganic phosphate, ionized calcium, total calcium, magnesium and creatinine and plasma 25-OH-D, 24, 25-(OH)₂D and 1,25-(OH)₂-D will be determined.

Progress During FY82: A careful analysis of our study of dietary phosphorus restriction in pseudohypoparathyroidism was published (attached). The results of our assay of 1,25-(OH)₂D in eight patients are being compared to the values obtained in another laboratory on the same sample. When this analysis is completed, the direction of this protocol will be defined (i.e., report the present data or study several more patients).

DATE: 8 Oct 81	Hase User No.:	1370	STATUS:	INTERIM	XXXX
STARTING DATE: 2	4 May 1977	DATE OF	COMPLETIC	1: 30 Sept	: 1985
KEY HORDS: Thyro	id, Estrogen,	Receptors			
TITLE OF PROJECT:	Sex steroid	receptors in th	e human	thyroid gla	nd
PRINCIPAL INVESTIG	GATOR(S): Rober	t A. Vigersky,	M.D.		
ASSCRIATE INVESTIG	GATOR(S):				
FACILITY: WRANC	• ·	DEPT/Svc: Kyle	Metabol	ic Unit	
Accumulative MEDC	ASE Cost: Ac	CURBLATIVE CONTRACT	Cost: /	ACCUMULATIVE S \$699.15	WPPLY COST:
FY-83 PECASE:	CONTRACT COST: \$500	SUPPLY COST:	DATE OF CO ANNUAL PRO	OWNITTEE APPRODERESS REPORT	FEB 2 5 1983
STUDY DEJECTIVE:					
	See Att	tached			
TECHNICAL APPROACE	<u>H</u> :				
	See Att	tached			
PROGRESS DURING F					
	See At1	tached			
Humsen of Subjects	s Studied:				
FY-82 <u>:</u>	TOTAL (TO	DATE):	BEFORE	COMPLETION OF	STUDY: 10
Serious/Unexpected	D SIDE EFFECTS IN	SUBJECTS PARTICIPAT	ing in Pao.	JECT (IF NONE S	STATE):
to access the p	eatients into	en perfected wit the study over	h other the succ	tissues and eeding 2 to	i the plan is
PUBLICATIONS OR AS	SSTRACTS FY-82:	None			

Study Objective: To determine whether the increased incidence of thyroid disease seen in women is due to abnormalities in the receptor for estrogen and/or androgen in their thyroid glands.

<u>Technical Approach</u>: Physio-chemical characterization of the sex steroid receptors to determine if any differences are present which may indicate a pathophysiology of the thyroid disorder.

Progress During FY82: None

DATE: 15Sep82 Hask User Ha.: 1374	STATUS: INTERIM Y FINE
	ATE OF COMPLETION: N/A
KEY NORDS: Infertility/Testosterone Title of Project: Evaluation of testost	anone receive in infertile men
THE COUNTY EVALUATION OF CESCOSC	erone reserve in intervite men
	· -
PRINCIPAL INVESTIGATOR(S): Allan R. Gla	ss. MD. LTC. MC
	ersky, MD, LTC, MC
FACILITY: MRAYE DEPT/SVC:	KMU
ACCUMPATIVE PEBCASE COST: ACCUMPATIVE COM	TRACT COST: ACCUMULATIVE SUPPLY COST:
93.601.0	· ·
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVED 052 5 1583
<u> </u>	PANNUM_ PROGRESS REPORT
STUDY OBJECTIVE: To explore androgen p infertile men.	roduction in various categories of
TECHNICAL APPROACH: Measurement of seru pituitary-testicular function.	m hormone levels during tests of
PROGRESS DURING FY-82: Approximately 6 n currently being completed for prepar	ew patients studied. Data analysis ation of new abstract and paper.
Number of Subjects Studied:	
FY-82: 6 TOTAL (TO DATE):	80 BEFORE COMMETTION OF STUDY: 100
Serious/Unexpected Side Effects in Subjects Pari None	TOTPATTES IN PROJECT(IF HONE SO STATE):
	s common, but mild, in men with oligo ogens is very complex and heterogeneo

PUBLICATIONS OR ABSTRACTS, FY-32:

Pertility Sterility 38:92, 1982 Additional abstract in preparation

DATE: 15Sep82	HORE LINET A	o.: 1379	Status	: Intering X	Final		
STARTING DATE: N/A DATE OF COMMETICAL N/A							
Key Kopps: puber	ty, under	nutrition					
TITLE OF PROJECT:	Effect of hormones	f post-weaning und in rats	ernutri	tion on repro	ductive		
PRINCIPAL INVESTIG	PATOR(s): A	llan Glass MD LTC	MC				
ASSOCIATE INVESTIG	ATOR(S):						
FACILITY: KRANC		DEPT/S/C: Endo	crinolo	gy-Metabolism			
Accumulative NECC	SE Cost:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE S			
FY-E 3 PECCASE:	CONTRACT COS	\$30,272,50 T: Supply Cost:	Dars as	\$28,148	00		
	27,000	15,000	ANNUAL	Committee APPROPRIES REPORT	FEB 2 5 1983		
	To explore function.	the effects of un	dernutr	ition in rats	on endocrine		
TECHNICAL APPROACH tests in under	· Predage.	ement of serum hor	mones a	nd endocrine	function		
PROGRESS DURING FY	-82: Highly	productive. 3 maj	or evne	riments on te	sticular function		
in nephrotic ra	its complet	ted; also 4 experi	ments of	n thyroid fun	ction in these rats		
HUMBER OF SUBLECTS		N/A	a study	or puberty o	n low protein diet.		
FY-82 <u>:</u>		(TO DATE):			~		
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NOME SO STATE):							
CONCLUSTONS:							
	nto a sing	on endocrine func gle model - furthe resting area.					
PUBLICATIONS OR ASS	TRACTS . FY-8	?:					
Papers published		ism 31:538, 1982			•		
	Endocri	nology 110:1542, 1	982				

Abstracts presented: Clinical Research 30:490A, 1982 Am J Clin Nutr 36:xviii, 1982

DATE: Oct 82	Mass Unit No.:	1380	STATUS	INTERIM X	Fire.	
START IS DATE: 1	9 October 1977	DATE OF	COYPLET	icii: 30 Septe	mber 1982	
Key Keens: Thyro	id Hormone, Cy	clic AMP, Cycl	ic GMP	·		
TITLE OF PROJECT:	Effect of Thy Responses of	roid Status or the Kidney	the Ho	ormonally Indi	uced Cyclic	AMP
PRINCIPAL INVESTI	GATOR(S): H. Li	inton Wray, COI	, MC	· ————		
ASSCRIATE INVESTI	GATOR(S): Wayma	an W. Cheatham,	MAJ,MC	Gerald S. K	idd,LTC, MC	
FACILITY: KRAYC		DEPT/S/C: Kyle	Metabo	ic Unit		
Accumulative MEDC	ASE Cost: Acc	TUHULATIVE CONTRACT \$7,000	Cost:	Accumulative S \$38,442	UPPLY COST:	
FY-83 PECCASE: \$5,000		Supply Cost: \$6,000	DATE OF PARHUAL	Comettee Appro Progress Report	FEB & 5 1983	
STUDY OBJECTIVE:	See Attache	ed				
TECHNICAL APPROAC	H: See Attache	ed				
Process Dualing F	<u>Y-82</u> : See Attach	ed				
Number of Subject	s Studied:			· · · · · · · · · · · · · · · · · · ·		
FY-82: 1	TOTAL (TO	DATE): 22	Befo	RE COMPLETION OF	STUDY: 30	
SERIOUS/UNEXPECTE	D SIDE EFFECTS IN	SUBJECTS PARTICIPA	ring in P	הטובכד(וד ווסווב s	STATE):	•
None		· .				
Conclusions: The	e delayed wate	r excretion in	hypoth	yroid patient	s and the d	ecrease
fractional exc	cretion of pho	sphate in hype n renal respon	rthyroi	d patients ar	e not assoc	iated
Push (CATIONS 02 A	BSTRACTS FY-82:	Am Soc Bone Mi	Res (Ahe) n 543 1	982 (attach	•4)

Study Objective: To determine if the renal hormone receptor - second messenger systems of two unrelated polypeptide hormones are affected by thyroid hormone. By measuring nephrogenous cyclic AMP during parathyroid and vasopressin infusions in hyper- and hypothyroid patients, it can be determined if thyroid hormone influence the renal cyclic AMP responses to these hormones.

Technical Approach: Hyperthyroid and hypothyroid patients will be admitted to Ward 47 for a 3 day study protocol and will be similarly studied after becoming euthyroid. During each admission the patient will undergo two 3-hour renal clearance procedures, one with PTH infusion and another with vasopressin infusion.

Progress During FY82: The data on the N-terminal PTH levels has been analyzed and compared with the C-terminal PTH levels during PTE infusion in hypothyroid and control subjects. All study results are being used in the writing of four papers and to determine the need for future studies. The PTH infusion data in two patients with borderline hypothyroidism was published in an abstract.

		 -		
DATE: 8 Oct 82 Max Unit No.:	1381	STATUS	: bexaggeon	Fro.
START INS DATE: 24 May 1977	DATE OF	COMPLET	ic:i: 30 Sep	t 1982
Key Monas: Estrogen, Recept	ors, Thyroid			~
TITLE OF PROJECT: Estradiol r		thyroi	i glands	
PRINCIPAL INVESTIGATOR(S): Robe	ert A. Vigersky,	M.D.		
ASSOCIATE INVESTIGATOR(S):		· 		
FACILITY: KRAYC	DEPT/S:c: Kyle	Metabo	lic Unit	····
ACCUMPLATIVE PEDCASE COST: /	ACCUINLATIVE CONTRACT			E SUPPLY COST:
FY-83 FEDCASE: CONTRACT COST:	Supply Cost:	DATE OF PHINNAL		PROVAL 02 RT FEB 2 5 1983
Study OBJECTIVE: See Attacho	ed			
TECHNICAL APPROACH: See Attache	ed			
Process During FY-82: See Attache	ed			
Nursex of Subjects Studies:				
FY-82: Not Appl. Total (1	TO DATE):	Befo	RE COMPLETION	OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS Not applicable	IN SUBJECTS PARTICIPA	ring in P	מסטַבָּכד(וּרְ וּיִּסִיּוּ	E SO STATE):
CONCLUSIONS: While prelimin in the thyroid of both mal estrogen receptors in other has greatly diminished thu	e and female rat r tissues, the i	s which	are simil to continu	ar to those of e these studies
Publications on Abstracts, FY-82:	None			

Study Objective: To study the nature of the extrogen receptor in the rat thyroid so that these studies can be used as a model for examining similar receptors in the human thyroid.

Technical Approach: Determination of the binding capacity, affinity, steroid specificity, net size and charge, sedimentation coefficient, etc. of the receptors obtained from the cytosol of male and female rats of varying age.

Progress During FY82: None

DATE: 8 Oct 1982 How Unit !	o.: 1382	STATUS	: INTERIM	KKKK	
STARTING DATE: 24 May 197	7 DATE OF	COMPLET	ici: 24 May	1983	
Key Koras: Micropuncture,	seminiferous tubul	e			
TITLE OF PROJECT: Measureme cats seminiferous tubules	nt of steroids and and epididymes.	fluid	obtained by	micropunctur	e from
PRINCIPAL INVESTIGATOR(S): R	obert A. Vigersky,	M.D.			
ASSOCIATE INVESTIGATOR(S): N	one			<u>-</u> -	
FACILITY: NRAYE	DEPT/Syc: Ky	le Meta	bolic Unit		
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT O	Созт:	AccumuLative \$9,442.3		
FY-83 FEECASE: CONTRACT COS	T: SUPPLY COST:	DATE OF INNUAL I	COMMITTEE LODS		}
Study OBJECTIVE:	Attached				
TECHNICAL APPROACH: See	Attached				
PROGRESS DURING FY-82:	Attached				
HUMBER OF SUBJECTS STUDIED:					
FY-82: Not appl. Total	(TO DATE):	BEFOR	E COMPLETION O	F Study:	
SERIOUS/UNEXPECTED SIDE EFFECTS Not applicable.	IN SUBJECTS PARTICIPAT	ing in Pa	DUECT(IF NONE	SO STATE):	
CONCLUSIONS: A blood testis arabinoside from entering a metabolic function for seminiferous tubule fluid	adrianycin so that	THEFT	The best		•

Publications or Abstracts, FY-82: Riccardi, R., Vigersky, R.A., Barnes, S., Blyer, W.A., and Poplack, D., "Micropuncture studies of the blood testes barrier to methotrexate in rats" Cancer Research, Vol 42:1617-1619, 1982.

Study Objective: To quantitate the levels of steroids in the seminiferous tubules and apididymes of the rat and to study the blood testis barrier for the steroids and other substances.

Technical Approach: Glass micropipets are used to obtain fluid from the above sites. The focus of last years work has been the completion of these studies to detect and quantitate the blood testis barrier to the antimetabolite methotrexate and cytosine arabinoside and to begin studies with adriamycin.

Progress During FY82: The studies on methotrexate and cytosine arabinoside have been completed and substantial progress has been made towards performing similar studies with adriamycin. The technical assistance of Dr. Bedanarik whose HPLC method for detection of adriamycin and its metabolites has made this work possible. We have found that only the aglycone of adriamycin is able to penetrate the blood testis barrier thus making adriamycin perhaps an ineffective agent for testicular cancers.

DATE: 8 Oct 82	Hass Ever No.	: 1386	STATUS	NTERIM X	Fire
STARTING DATE: 2	2 Nov 1977		DATE OF COMPLET	ic:i: 30 Se	pt 1983
Key Voras:					
TITLE OF PROJECT:	The effect	of A-1-tes	tolactone (t	eslac) in ma	le infertility
PRINCIPAL INVESTI	GATCR(S): Rob	ert.A. Viger	sky, M.D.		
ASSOCIATE INVESTI	GATOR(S):				
FACILITY: WRANG	·	DEPT/SVC:			
Accumulative PECC \$2,000	ASE Cost:	Accure Ative Co \$49,707.6	DITRACT COST:	AccumuLative \$ \$18,255.38	
FY-83 FEECASE:	CONTRACT COST \$1,500	: Supply Cost \$3,000	DATE OF ANNUAL	COMMITTEE APPRI PROGRESS REPORT	OFE 2 5 1993
STUDY OBJECTIVE:	See Atta	c hed	· · · · · · · · · · · · · · · · · · ·		
TECHNICAL APPROAC	면: See Atta	ched			
PROGRESS DURING F	Y-82: See Atta	ched			
Humaen of Sualect	rs Stronten: (
FY-82: 8	TOTAL	(TO DATE):	25 BEFO	RE COMPLETION O	₹ \$700Y: 30
Serious/Unexpecta	D SIDE EFFECTS	IN SUBJECTS PA	RTICIPATING IN P	ROJECT(1F HONE	SO STATE):
the sperm coun	nts and fert which this o	ility in me	n with idiop	athic oglios	n in improving permia. The the androgen/
PUBLICATIONS OR A	STRACTS. FY-8	2: None		·····	

Study Objective: To improve sperm counts infertility in men with idiopathic ogliospermia and to study the mechanism by which these men have diminished sperm counts.

Technical Approach: LRH and HCG tests are performed before and at the completion of treatment with teslac 1 gm per day and tamoxifen 20 ml per day orally. Semen and hormonal parameters are monitored monthly as well as screening for the toxicity of the drugs.

Progress During FY82: An additional 10 men have now been entered into the study. The results of the hormonal parameters comparing the effects of teslac and tamoxifen to teslac alone are currently undergoing analysis. The preliminary analysis of the semen data and pregnancy rate indicates that the addition of tamoxifen has not substantially improved either. There is an improvement in sperm count in approximately 90% of the men and a fertility rate of 35% in the couples.

DATE: 210ct82 HOPK UNIT NO	o.: 1391	STATUS: INTERIM X	Freeze
STARTILE DATE: January 19	978 DATE OF	COMPLETION: 1982	
KEY MORDS: T3 Receptors		· · · · · · · · · · · · · · · · · · ·	
Title of Project: Regulation	on of the Initiation	n of Thyroid Horm	one Action
PRINCIPAL INVESTIGATOR(S): K	enneth D. Burman, L	TC, MC	
ASSOCIATE INVESTIGATOR(S): L	eonard Wartofsky, Co	OL, MC, Keith Lat	ham, Ph.D., Yvonne Lukes
FACILITY: WRANC	DEPT/SVC:		
ACCUMILATIVE PEDCASE COST:	Accumulative Contract C	OST: ACCUMULATIVE	SUPPLY COST:
FY-83 I'EDCASE: CONTRACT COS		DATE OF COMMITTEE APP ANNUAL PROGRESS REPOR	FEB 2 5 1983
STUDY OBJECTIVE: To investi their activity.	gate the mechanism	by which thyroid	hormones exert
TECHNICAL APPROACH: To isoland nucli from liver and	to assess their pu	rity by gell elec	trophoresis and
HPLC. These receptors a	re then purified as	well as possible	! .
PROGRESS DURING FY-82: We, i receptor and are present the receptor is made of	ly making antibodie	s against this pr	otein. It appears
Murber of Subjects Studied:			etylase perferring
FY-82: TOTAL	(TO DATE):	BEFORE COMPLETION	component. of Study:
SERIOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPATI	NG IN PROJECT(IF NONE	SO STATE):
None	·		
Conclusions: Receptor has	acetylase activity	in the amount of	50,000 daltons.

PUBLICATIONS OR ABSTRACTS. FY-82: Presentation at the American Thyroid Association September 1981 and paper by Burman, Lukes, Latham and Wartofsky, "Ipodate and ANS Block Receptor Binding of T3 in Rat Liver", Hormone and Metabolic Research

DATE: 210ct82 HORK UNIT N	0.: 1393	STATUS	: INTERIM X FIRM				
STARTING DATE: 1978	DATE OF	COMPLET	ION: 1982				
Key Nords: T3 Receptors/ Fasting							
TITLE OF PROJECT: T3 Recep	otors in Normal and	Fasti	ng Rats				
PRINCIPAL INVESTIGATOR(s): Kenneth D. Burman, LTC, MC							
ASSOCIATE INVESTIGATOR(S):	Yvonne Lukes						
FACILITY: NRAYE	DEPT/SVC:						
Accumurative PEDCASE Cost:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE SUPPLY COST:				
			·				
FY-83 I'EDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF	COMMITTEE APPROVAL OF PROGRESS REPORT FEB 25 1983				
		LIANOPL	TROSRESS REPORT FEB 25 1983				
STUDY OBJECTIVE: To determ	ine if T3 receptors	and T	SH receptors decrease				
during fasting.							
TECHNICAL APPROACH: Thyroid	glands are isolate	d from	20-40 rats and a hemogenate d TSH is added. A Scatchard				
prepared. The memoranes	s are isolated in land and number of recei	tor si	tes determine.				
Page 22 Practic FY-82. We ha	ave performed studi	es on	approximately 100 rats				
during the fed and fast receptors increase, alt	ing period and dete	rmined	that the number of TSH				
Minser of Subjects Studied:	Rat Study	1 Tevel	s decrease.				
HOLDER OF COSCETS CHAPTED:	•	D					
FY-82: TOTAL (TO DATE): BEFORE COMPLETION OF STUDY:							
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPAT	ing in P	ROJECT(IF NONE SO STATE):				
None							
CONCLUSIONS: Fasting associated with the number of TSH receptors in the thyroid gland. We are presently investigating the mechanism by which this occurs.							
•							
PUBLICATIONS OR ABSTRACTS, FY-	82:						

DATE: 210ct82 HORK UNIT A	io.: 1395	STATUS	INTERIM X	FINAL			
STARTING DATE: 1978 DATE OF COMPLETION: 1982							
KEY NORDS: Glucose/T4 Co				·			
TITLE CF PROJECT: T4 to Metabolism	T3 Conversion: Effe	ct of	Modulation of	Glucose			
PRINCIPAL INVESTIGATOR(S):	Kenneth D. Burman	. LTC.	МС				
ASSOCIATE INVESTIGATOR(S):	Robert C. Smallridg	e, LTC	, MC				
FACILITY: HRANC	DEPT/Svc: Dept	of Me	d/KMU				
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Созт:	ACCUMULATIVE S	UPPLY COST:			
FY-83 i/EDCASE: CONTRACT COS).WHUAT	COMMITTEE APPROPRESS REPORT	FER 2.5 1987			
Study OBJECTIVE: To study conversion in humans an	the mechanism by wh d in rat liver.	ich gl	ucose enahnce	es T4 to T3			
TECHNICAL APPROACH: Hepatic T4 is added to these prassay. Various modulati	reparations. The an	ount c	f T3 is measu	red by radio	oimmuno-		
Prosess During FY-82: We henzyme activity and are	ave shown that sulf	hydryl	groups in g	ucose increa	ase		
MUMBER OF SUBJECTS STUDIED:	Rat Study						
FY-82: TOTAL	(TO DATE):	BEFO	RE COMPLETION OF	ציניטיץ:			
SERIOUS/UNEXPECTED SIDE EFFECT None	'S IN SUBJECTS PARTICIPAT	ing in b	ROJECT(IF NONE S	O STATE):			
CONCLUSIONS: Glucose enh	ances T4 to T3 conv	ersion	•				
PUBLICATIONS OR ABSTRACTS. FY-	82: None Yet.						
Technical Approach			ermine whe		Т3		

DATE: 210ct82	HORK LINET NO	o.: 1396		STATUS	INTERIM	X F	1829.	
STARTING DATE:	1978		DATE OF	COMPLET	ION:	198	32	
Key Words: T4 t	Key Words: T4 to T3 Conversion/Somatostatin							
TITLE OF PROJECT:	T4 and T	3 Conversi	on: Effe	ct of S	omatosta	tin Adı	ninistration	
PRINCIPAL INVESTIG		Kenneth D.	Burman,	LTC. M	ic			
ASSOCIATE INVESTIG	SATOR(S):							
FACILITY: WRANC		DEPT/SI	/C:					
Accumulative MEDO	4SE Cost:	ACCUMULATIVE	CONTRACT	Cost:	ACCUMULAT	IVE SUPP	LY COST:	
FY-83 PEDCASE:	CONTRACT COST	r: Supply Co	OST:	DATE OF FAMUAL F	COMMITTEE PROGRESS RE	PPROVAL	0 = 8 2 5 1983	
STUDY OBJECTIVE: To determine if somatostatin alters T4 conversion and T3 receptors and to determine if somatostatin receptors are altered by thyroid hormone levels. TECHNICAL APPROACH: Somatostatin receptors are measured in thyroid and pituitar gland as well as peripheral red cells and white cells. These receptors are measured and kinetics analyzed in various states of thyroid function. PROGRESS DURING FY-82: We have had difficulty developing an assay to measure somatostatin receptors in thyroid and pituitary glands and we are not sure								
at the present	time whet	her it is	just non	-sepcif	ic bindi	ng.		
HUMBER OF SUBJECTS	: Sייסונם: r	at study						
FY-82 <u>:</u>		(TO DATE):						
SER LOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS	PARTICIPAT	ing in Pa	OJECT(IF N	ONE SO S	TATE):	
None CONCLUSIONS: Non	e yet.	<u> </u>						
PUBLICATIONS OR AB	STRACTS. FY-8	2: None	yet.					

DATE: 20 Oct 82 HOPK UNIT N	0,: 1397	STATUS	: INTERIM X	Final		
STARTING DATE: 1979	DATE OF	COMPLET	10H: 1984	<u> </u>		
	ondition/T3 Recept		·			
TITLE OF PROJECT: The Effect Circulating Mononuclear		olic Co	onditions on	T3 Receptors		
PRINCIPAL INVESTIGATOR(S):	Kenneth D. Burman.	LTC.	МС			
ASSOCIATE INVESTIGATOR(S):						
FACILITY: HRAYC	DEPT/Svc:			**************************************		
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE	SUPPLY COST:		
FY-83 I'EDCASE: CONTRACT COS	T: Supply Cost:	DATE OF	COMMITTEE APPR PROGRESS REPORT	oval Of FEB 2.5 19 23		
STUDY USUSCTIVE: To determ various metabolic condit	ions.					
TECHNICAL APPROACH: The obt Hypaque isolation and me	aining and separateasuring by Scatcha	ing of ird Ana	T3 receptors lysis of T3 a	s by Ficol1 and T4 receptors.		
PROGRESS DURING FY-82: We have techniques. T3 receptors both of these states are	s in diabetes and c	irtica	l illness and	d it appears that		
Munser of Subjects Studied:						
FY-82: 20 TOTAL	(TO DATE): 30	Befo	RE COMPLETION O	F STUDY: 50		
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF HONE SO STATE): None						
CONCLUSIONS: T3 receptors are decreased in circulating white cells.						
•						
Publications or Abstracts, FY-sand under evaluation.	32: Manuscript sub	nitted	to the Journ	al of Endocrinology		

DATE:300ct82	Hosk Unit He	o.: 1398	s	SIATUS: IA	TERIN X	Fire.
STARTING DATE: J	une 1978		DATE OF CO	XFLETIC:1:	30 Septe	mber 1983
Key Voges: Hypo	calcemia,	osteoblasts	, cancer			
TITLE OF PROJECT:				hypocal	cemia in	tumors
associated wit	associated with osteoblastic metastases					
PRINCIPAL INVESTI	GATOR(S): H.	Linton Wray	, COL,MC,	Robert	C. Small	ridge,LTC,MC
ASSOCIATE INVESTI	GATOR(S): Che	etham, LTC(P) MC			
FACILITY: WRAYE	•	DEPT/SVC	Kyle M	<u>letaboli</u>	Unit	
ACCUMPLATIVE PEDC	ASE Cost:	Accumulative No		st: Acc	CUMULATIVE S \$8919	SUPPLY COST:
None FY-83 FECASE:	CONTRACT COS			ATE OF COM	NITTEE APPRO	
\$5000	\$1000	\$2500	Ĭ.	NNUAL PROS	RESS REPORT	FEB 2 5 1983
See Attached TECHNICAL APPROACH: See Attached						
PROGRESS DURING F	Y-82: See A	ttached				
HUMBER OF SUBJECT	s Stroted:					
FY-82: 0	Total	(TO DATE):	0	BEFORE CO	CHELETICH O	F STUDY: 8
Serious/Unexpecte	D SIDE EFFECT	s in Suauects P	ARTICIPATIO	s in Prouse	י בויסוו או) דכ	SO STATE):
Conclusions:						
. De	ferred					
PUBLICATIONS OR A	BSTRACTS, FY-	32: None				

Study Objective: To determine whether the hypocalcemia seen in some patients with osteoblastic metastases is due to hypoparathyroid, secondary hyperparathyroidism with an abnormality in vitamin D metabolism, or an unidentified humoral substance with osteoblastic activity.

Technical Approach: (1) 24 hour urines for calcium, phosphate, creatinine and other substances.

(2) Serum for Ca, PO4, Mg, alkaline phosphatase, parathyroid, vitamin D metabolites and other substances.

(3) Calcium and parathormone infusions

(4) Bone marrow biopsies for tissue culture to test in vitro the cells' ability to incorporate 'H-proline into collagen.

Progress During FY82: Vitamin D metabolite assays were standardized.

DATE: 140ct82	Hask User No	.: 1399	SIATUS	: INTERIM	x Fro	
STARTING DATE: M	ay 1978		DATE OF COMPLET	ich: 30 Se	ptember	1983
Key Moss: Parat	hormone					
TITLE OF PROJECT:	An assessm	ent of parat	hyroid hormo	ne (PTH)	levels :	in normal
subjects and i	n patients	with disorder	rs of calciu	m metabol	ism.	
PRINCIPAL INVESTI	GATOR(S):H.Li	nton Wray,CO us Schaaf, M	L,MC, Robert	C. Small	ridge,L	CC,MC
ASSOCIATE INVESTI	GATOR(S):				·	
FACILITY: WRAYS		DEPT/S/C:	Kyle Metal	olic Unit		
Accurative MEDC	ASE Cost:	Accumpative Co.	TRACT COST:	ACCUMULAT (\$94.54)	IVE SUPPLY	Cost:
FY-83 PECASE: \$5000	CONTRACT COST \$1800	: Supply Cost: \$3000	DATE OF ANNUAL	COMMITTEE P PROGRESS REP	PPROVAL O	<u>2 5 1983</u>
Study Objective:	To establis ith metabol	h the ranges ic disorders	of serum P	H levels	in norma	l subject
TECHNICAL APPROAC Nichols Instit an assay using	ute kit has antisera o	been utilize f proven cli	ed in the pa nical use wh	ist. We a hich has b	re now d	ieveloping vided by
PROGRESS DURING F	Analysi	s of data fr	om 75 sample	s showed	the Nich	hols
Institute kit		or only mar	ginal useru	ness.		
Number of Subject						
FY-82: 30	TOTAL	(TO DATE): 1	10 BEFO	RE COMPLETIO	יפטד2 הס ווכ	y: 200
Serious/Unexpecte	D SIDE EFFECTS	IN SUBJECTS PAR	TICIPATING IN P	ROUECT(1F NO	ONE SO STA	τε):
Conclusions:	ferred					
Publications of A	satracts. FY-8	2: "				
FOCIONIONS OF N	DUINNOISE ET O	2. None				
Technical Ap	proach (c	ontinued)	Dr. L. E. Medical (te of E	Baylor

DATE: 20 Oct 82 HORK UNIT N	o.: 1300-78	STATUS: INTERIM X FINAL
STARTILE DATE: 1978	DATE	OF COMPLETION: 1982
NET NOISS.	ine/Immunoassay	
TITLE OF PROJECT: The Deve	lopment of a Radi	ioimmunoassay of Triiodothyronine
PRINCIPAL INVESTIGATOR(S): K	enneth D. Burman,	, LTC, MC
ASSOCIATE INVESTIGATOR(S):		
FACILITY: MRAYE	DEPT/SVC:	
ACCUMULATIVE PEDCASE COST:	ACCUMBLATIVE CONTRAC	CT COST: ACCUMULATIVE SUPPLY COST:
FY-83 I'EDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEE 25 1923
TECHNICAL APPROACH: Rabbits are bled 3-6 months late PROGRESS DURING FY-82: Antib	are injected witer.	phistocated material such as TSI, th conjugate and the hapten and t tly being generated against thyrowhich causes hyperthyroidism.
HUMBER OF SUBJECTS STUDJED:	Animal Protocol	
FY-82: None Total	(TO DATE): None	BEFORE COMPLETION OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS None	IN SUBJECTS PARTICIPA	NATING IN PROJECT(IF NONE SO STATE):
Conclusions: None yet.		
·		
PUBLICATIONS OR ABSTRACTS, FY-8	2: None	

DATE: 8 Oct 82 Mark Unit !	a.: 1303 - 78	STATUS: TANKERSK	Fire
STARTING DATE: 9 June 1978	BATE OF	COMPLETION: 1 Octo	ber 1982
KEY KORDS: Hypothyroidism.	Drug Metabolism		
TITLE OF PROJECT: Studies:	in the Alterations	of Drug Metabolis	m in Hyperthyroidism
PRINCIPAL INVESTIGATOR(S): ROI	pert A. Vigersky MD	, Kenneth Burman	MD, Leonard Wartofsk
ASSOCIATE INVESTIGATOR(S): JOS	seph Bruton, Robert	Smallridge, Jack	O'Brian
FACILITY: KRAYC		Metabolic Unit	
Accurative PEDCASE Cost:	ACCUINLATIVE CONTRACT (None		
FY-83 PECCASE: CONTRACT Cos	T: SUPPLY COST:	DATE OF COMMITTEE APPLEMENTAL PROGRESS REPOR	FEB 2 5 1983
STUDY OBJECTIVE: See Att	ached		
TECHNICAL APPROACH:		· · · · · · · · · · · · · · · · · · ·	
See Att	ached		
PROGRESS DURING FY-82:		 	
See Att	ached		
Hursen of Subjects Studied:			
	(TO DATE): 2		
Serious/Unexpected Side Effects None	S IN SUBJECTS PARTICIPATI	ng in Project(is none	SO STATE):
Conclusions: Our second yethe completion of this preferminated.	ar fellow, Anthony otocol and thus we	Zavadil decided rare requesting the	ot to pursue wat it be
Puse ATIONS OR ABSTRACTS FY-8	2: None		

Work Unit No: 1303-78

Study Objective: To determine if changes in metabolism of drugs used to treat hypothyroidism are due to the elevated thyroxine levels per se or mediated through beta adrenergic affects.

Technical Approach: Methimazole and dexamethasone clearance rate will be determined in ten hyperthyroid subjects before therapy while on beta blockade and when ultimately euthyroid. Cardiovascular status will be monitored by assessment of ejection fraction and cardiac output using radionuclide imaging.

Progress During FY82: None

DATE: 8 Oct. 82 HORK UNIT	lo.: 1304-78	Status	: INTERIM X FIRM	V.
STARTING DATE: July 1978	DATE OF	F COMPLET	ION: 2-3 years	
Key Kers: Acromegaly/car	diac function		·	
	clide Assessment of romegaly	Cardi	ac Function in Pat	:ients
with Ac			<u> </u>	
PRINCIPAL INVESTIGATOR(S): R	obert C. Smallridge	LTC	мс	
ASSOCIATE INVESTIGATOR(S): M	. Schaaf, M.D.; S.	Raible	, MAJ MC; D. VanNo	ostrand, LTC MC
FACILITY: HRAYC	DEPT/Svc: Media	ine/En	docrinology	
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE SUPPLY 1,400.00	Cost:
FY-83 I'EDCASE: CONTRACT CO	ST: SUPPLY COST:	DATE OF FINNUAL	COMMITTEE APPROVAL OF PROGRESS REPORT FEB	: 2 5 1983
STUDY USJECTIVE: To determine ventricular function. TECHNICAL APPROACH: Multigate before and after bicyconcedure involves in procedure involves in procedure exercise, to locate the procedure exercise, to locate the procedure exercise.	ted radionuclide and le exercise to evaluation of 99-technorotocol was modified	ngiogra luate c etium to	phy (MUGA) scans a ardiac contractili o label human red tudy subjects befo	are done ity. This blood cells. ore and ion.
Mumber of Subjects Studied: FY-82: 12 Tota	L (TO DATE): 30	Befo	RE COMPLETION OF STUDY	Open ended - all new acromegalic :patients
SERIOUS/UNEXPECTED SIDE EFFECTIONS CONCLUSIONS:				
Data are being analyze	ed.			
PUBLICATIONS OR ABSTRACTS, FY	-82:			
None				

CISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

SGRD-UWH-D

Review of Annual Progress Reports (APR)

TO C, Clinical Invest Svc, WRAMCFROM C, Dept Clin Phys, WRAIRDATE 10 Dec 82

CMT 1

LTC Smallridge/cy/63014

¢ 0.8. GOVERNMENT PRINTENG OFFICE: 1902-372-711

- 1. The following information is provided in response to the reviewer's comments on my APR for Work Unit 1304-78;
- a. The completion date is not open ended. Please note on line two of the APR that a date of completion of 2-3 years is expected. What is open ended is the number of new patients to be studied during that time, since the number of new acromegalics who will be arriving at our institution is unknown. The original protocol submitted and approved in 1978 did not specify an exact number of patients to be examined.
- b. I take umbrage at the reviewer's comment "no conclusion after 4 years!". Had he read our APRs for 1980 and 1981 he would have seen our conclusions based on our experience using rest MUGA scans. Our previous APR also referred to our published abstract (Clin Res 28: 198A, 1980). An addendum to this protocol was submitted to the CIS (see DF of 17 Aug 81, copy attached) and was approved to change our protocol to study patients using exercise MUGA scans. The conclusions in our 1982 APR refer only to the achievements relating to our revised study. We are quite pleased that twelve patients were studied in the past year, and do not find it unreasonable to defer any conclusions until more patients are examined and the data analysis is finalized.

Incl

ROBERT C. SMALLRIDGE, M.D.

LTC. MC

Chief, Dept of Clinical Physiology

WRAIR

DISPOSITION FORM

For use of this form, soo AR 340-15, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSWP-ME

Addendum to Protocol, Work Unit # 1304-78

TO C, Clin Invest Svc, WRAMC

FROM C, Dept Clin Physiology, DATE 17 August 1981 CMT I WRAIR

- 1. During the past 2 1/2 years, radionuclide multiple gated acquisition (MUGA) scans have been performed on many of our acromegalic patients under the auspices of a protocol entitled "Radionuclide Assessment of Cardiac Function in Patients with Acromegaly." A preliminary report of the data (Mutter, Smallridge, Oetgen, et al. Clin Res 28:198A, 1980) has suggested that some patients with acromegaly may have impaired left ventricular (LV) function. A more sensitive measure of LV function can be obtained by performing MUGA scans before and after bicycle exercise, a technique only recently available at WRAMC.
- 2. Request permission to change our protocol to permit performance of exercise MUGA scans. The details of this procedure have been outlined in another protocol (Work Unit #8051) and the appropriate methodologic considerations and radiation dosimetry are attached to this DF. Also attached is a revised Patient Consent Form for this procedure.

Robert C. Smalfrude. ROBERT C. SMALLRIDGE, M.D.

LTC, MC

Chief, Department of Physiology

WRAIR

DATE: 8 Oct. 82 HORK UNIT No.: 1305-78			: INTERIM X FIRST
STARTING DATE: July 1978	COMPLET	TON: Early 1983	
KEY WORDS: Thyroid hormone	/breast cancer		•
Time of Project: Breast ca	rcinoma and thyroi	d hormo	one receptors
PRINCIPAL INVESTIGATOR(S): RO		, LTC N	ac
ASSOCIATE INVESTIGATOR(S): Ke	ith Latham, Ph.D.		
FACILITY: WRATE	DEPT/Svc: Medic	ine/Enc	ocrinology
ACCUMULATIVE PEDCASE Cost:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE SUPPLY COST:
FY-83 i EDCASE: CONTRACT COS	T: SUPPLY COST: 200.00	DATE OF ANNUAL	COMMITTEE PPROVAL 02 5 1983
STUDY COJECTIVE: To determ identified in human bro	ine whether thyroiceast carcinomas	d hormo	ne receptors can be
TECHNICAL APPROACH: Breast to in a receptor binding as	umor is frozen in : ssay (Latham <u>et al</u>	liquid . <u>J Bi</u> o	nitrogen and processed 1 Chem 251:7388, 1976)
PROSRESS DURING FY-82: Review	wers of manuscript	have r	equested additional data.
MUMBER OF SUBJECTS STUDIED:			
			RE COMPLETION OF STUDY: 7
SERIOUS/UNEXPECTED SIDE EFFECTS	IN SUBJECTS PARTICIPAT	ing in Pi	ROJECT(IF NONE SO STATE):
CONCLUSIONS: Thyroid hormon Several additional sampl present results, a prosp submitted for review in	les will be examine pective study is be	ed earl	y in FY 83. Based on
PUBLICATIONS OR ABSTRACTS, FY-8	2:		
None			

DATE: 21 Oct 82 MORK UNIT N	o.: 1307-78	STATUS: INTERIM X FINAL
START IN DATE: 1979	DATE OF	COMPLETION:
Key WORDS: Fasting/TSH		
	ect of Fasting Upon	n TSH Response to TRH
PRINCIPAL INVESTIGATOR(S):	Kenneth D. Burman.	LTC, MC
ASSOCIATE INVESTIGATOR(S):	·	
FACILITY: WRANG	DEPT/SVC:	
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:
Circle State of the Control of the C		
FY-83 PEDCASE: CONTRACT COS	T: SUPPLY LOST:	DATE OF COMMITTEE APPROVAL DE 2 5 1983 ANNUAL PROGRESS REPORT FEB 2 5 1983
decreased in fasting. TECHNICAL APPROACH: Measure after TRH stimulation du	ement by immunoassa uring fed and fasti	
patients but they have r normal.	ous carbohydrate an not been able to st	d fat contents have been fed to imulate the TSH response back t
MUMBER OF SUBJECTS STUDIED:		
FY-82: 15 TOTAL	(TO DATE): 20	BEFORE COMPLETION OF STUDY: 30
None	s in Subjects Participat	ING IN PROJECT(IF HONE SO STATE):
CONCLUSIONS: None		

Publications or Abstracts, FY-82: Forsham Address, Annual Meeting of the Military Society of Endocrinology, June 1982

DATE: 210ct82	WORK UNIT NO.:	1300-79	STATUS	INTERIM	Х	FireL
START 1:45 DATE:	18 Aug 80	DATE OF	COMPLET	ION:	15 A	ug 83
KEY KORDS: HPL	C/Iodothyroni	nes				
TITLE OF PROJECT:	Measurement	of Iodothyronia	nes by	HPLC		
			•			
PRINCIPAL INVESTI	GATOR(s): Ken	neth D. Burman,	LTC, M	C		
ASSOCIATE INVESTI	GATOR(S):					
FACILITY: WRANC		DEPT/SVC:				
Accumulative MEDC	ASE Cost: Ac	CUMULATIVE CONTRACT	Cost:	ACCUMULAT	ive Su	IPPLY COST:
FY-83 I/EDCASE:	CONTRACT COST:	SUPPLY COST:	DATE OF	COMMITTEE PROGRESS RE	APPROV PORT	AL OF FEB 2 5 1983
and to use HPL disease. TECHNICAL APPROAC a column in mo PROGRESS DURING F performed and	C as tool to H: Either se Tecular weigh Y-82: HPIC of Correlated we	if serum T3 and separate protein rum extracts or t in number of protein T3 and T4 can be all with radioim ification techn	recept protein e perfo munoass	or extraction peaks de	cts a	muno thyroid re placed on ined. and has been
HUMBER OF SUBJECT	s Studied:					
FY-82: 30	TOTAL (TO	DATE): 40	Befor	E COMPLETI	on of	STUDY: 50
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(1F NONE SO STATE):						
CONCLUSIONS: HE method to RIA.		d to measure T3	and T4	in seru	n as	an alternative
PUBLICATIONS OR A	BSTRACTS, FY-82:					

DATE: 21 Oct 82 NORK UNIT N	o.: 1301-79	STATUS: INTERIM X FIRM		
STARTING DATE: 1 Jan 79	DATE O	of Completion: 1 Jan 84		
KEY MORDS: Metabolic Con	dition/T3 Receptor	ors		
TITLE CF PROJECT: Effect of Various Metabolic Conditions and T3 Receptors on Circulating Cells				
PRINCIPAL INVESTIGATOR(s): Kenneth D. Burman, LTC, MC				
ASSOCIATE INVESTIGATOR(S):				
FACILITY: KRAYC	DEPT/SVC:			
ACCUMULATIVE PEDCASE COST: 3,000.00	Accumulative Contract 5,338.70	T COST: ACCUMULATIVE SUPPLY COST: 39,158.92		
FY-83 PEDCASE: CONTRACT COS		DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FED 2 3 1383		
STUDY OBJECTIVE: To determi various metabolic condit		rs in white cells are altered in		
		ting of T3 receptors by Ficoll mard Analysis of T3 and T4 Receptors.		
techniques. T3 receptor	s in diabetes and	sing solubilized and unsolubilized critical illness and it appears with decreased number of receptors.		
MUMBER OF SUBJECTS STUDIED:				
FY-82: 20 TOTAL	(TO DATE): 30	BEFORE COMPLETION OF STUDY: 50		
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE):				
CONCLUSIONS: T3 receptors are decreased in circulating white cells.				
·				
Publications or Abstracts, FY-8 and under evaluation.	2: Manuscript su	submitted to the Journal of Endocrino	logy	

DATE: 8 Oct 82	Hask Burr No	.: 1302-7	9		INTERIM	<u> </u>	
STARTING DATE: 2	4 April 19	79	DATE O	F COPPLET	Request C:D4 April	to extend	this to
Key Voros: Hodgk	in's Disea	se. Steri	lity Go	nadal D	атаде		
Title of Project: Chemotherapy fo	Prevention	of Gonada	al Damag	e in Me	n Treated		ination
PRINCIPAL INVESTIG	ATOR(S): Rob	ert A Vig	ersky. N	D. Jeff	rey Berenl	ourg. M.D.	
ASSOCIATE INVESTIG	ATOR(s):			•			
FACILITY: HRANG	·	DEPT/S	vc: Kyle	Metabol	ic Unit, I	lemotology	/Oncology
Accumulative MEDU \$3875	SE Cost:	AccumuLativ \$11		Cost:	ACCUMULATI \$283.55	VE SUPPLY COS	;T:
FY-83 PEDCASE:	CONTRACT COST \$10,000			DATE OF PURIOR	Committee A Progress Rep	PPROVAL 0= CRT FEB 2	<u>5 198</u> 3
STUDY DBJECTIVE:	See	Attached					
TECHNICAL APPROACE	-	Attached					
PROGRESS DURING F	<u>Y-82</u> :						
	See	Attached					
Number of Subject	ς \$τυσιεσ: ͺ						
FY-82: 21	Total	(TO DATE):	35	Befo	RE COMPLETIO	א סד Sדעפע <u>ז:</u>	50
SERIOS UNEVECTE	D SIDE EFFECTS	in Suauects	PARTICIP.	ATING IN P	houset(if he	DNE SO STATE)	:·····································
Conclusions: Mer	with Hode	kin's Dis	ease ha	ve pretr	eatment a		es
of gonadal function of gonadal functions and to other malignance Disease.	ction sugge the testis.	stive of This is	a combin	ned abno ly diffe	rmality of them	f both the patients	with

PUBLICATIONS OR ABSTRACTS, FY-82: Vigersky RA, Chapman RM, Berenburg J, and Glass AR, "Testicular Dysfunction in Untreated Hodgkin's Disease", American Journal of Medicine, October 1982.

Work Unit No: 1302-79

Study Objective: To prevent the germ cell and leydig cell damage induced by combination chemotherapy in the treatment of Hodgkin's Disease and Histiocytic Lymphoma.

Technical Approach: Men with the above diagnoses are treated before induction of chemotherapy with testosterone annanthate 200 ml i.m. weekly for at least two weeks in order to suppress their testis. Sperm counts and a short HCG test are performed before and after cessation of chemotherapy (approximately 6 months later).

Progress During FY82: Of the four patients eligible for this protocol during this past fiscal year only I patient was entered because their was refusal on the part of two and one had to be treated on an emergency basis. In addition nine patients with Hodgkin's Disease and eleven patients with other malignancies were tested with semen analysis and short HCG tests prior to their therapy.

DATE: 250ct82	HORK UNIT NO	1304-79	STATUS	: INTERIM	X Firms
STARTING DATE:		Dat	E OF COMPLET	ION:	
Key Horas:					
TITLE OF PROJECT:	Thyroid Ho	ormones in Cere	brospinal	Fluid	
			•		
PRINCIPAL INVESTIG	CATOR(s): K	enneth D. Burma	n, LTC, M	C	
ASSOCIATE INVESTIG	SATOR(S): p-	rentice Thompso	n. LTC. M	<u> </u>	
FACILITY: WRANC		DEPT/SVC:	KMU		
Accumulative PEDC	©E Cost:	ACCUMULATIVE CONTR	ACT COST:	ACCUMULATI	VE SUPPLY COST:
FY-83 FEDCASE:	CONTRACT COST	: Supply Cost:	DATE OF	COMMITTEE A	PPROVAL OF ORT FEB 2.5 1983
STUDY OBJECTIVE:	To measure	thyroid hormo	ne levels	in CSF.	
		-			•
TECHNICAL APPROACH		obtained from r	outine cl	inical sam	ples and T3/T4
PROGRESS DURING FI	'- 8 2:				
Number of Subjects	STUDIED:				~
FY-82: 30		(TO DATE): 30	Вего	RE COMPLETION	4 OF STUDY: 30
SERIOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PARTIC	PATING IN P	ROJECT(IF NO	WE SO STATE):
None					
CONCLUSIONS: T3	, T4, and	rT3 exist in CS	F.		
PUBLICATIONS OR AB	STRACTS, FY-82	: JCEM			

		
DATE: 15 Sept 82 Now Unit I	STATUS: INTERIM X FIRM	
STARTING DATE: N/A	DATE OF	COMPLETION: N/A
KEY NORDS: amenorrhea, st	ress	
TITLE OF PROJECT: Stress-in	nduced amenorrhea in	military cadets.
PRINCIPAL INVESTIGATOR(S):	Allan Glass MD LTC M	vic
ASSOCIATE INVESTIGATOR(S):	Leigh Wheeler MD LTC	C MC
FACILITY: MRAYC	DEPT/Syc: Endocr	rinology-Metabolism
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT C	COST: ACCUMULATIVE SUPPLY COST:
0	<u> </u>	. 0
FY-83 FEDIASE: CONTRACT COS	it: Supply Cost:1_500	DATE OF COMMITTEE REPROVAL DE 198
		menorrhea which develops in
female Wes	t Point cadets	
TECHNICAL APPROACH: Performan	nce of ovarian funct	tion tests in normal and
amenorrheic female West	Point cadets.	
		to recruit volunteers- no
cadets volunteered. One recruiting effort in FY-		left. Will consider another
HUMBER OF SUBJECTS STUDIED:	<u> </u>	
FY-82: 0 Total	(TO DATE): 0	BEFORE COMPLETION OF STUDY: 15
SERIOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPATIO	NG IN PROJECT(IF NOWE SO STATE):
Conceustons:	·	· · · · · · · · · · · · · · · · · · ·
Deferred-no da	ta yet	
•		
PUBLICATIONS OF ABSTRACTS FY-S	ກ.	
PUBLICATIONS OR ABSTRACTS, F1-6)Z:	
None		

DATE: 8 Sept 82 Hook User M	o.: 1310 - 79	STATUS:	INTERIM	FROCKEX	
STARTING DATE: 3 July 19	80 DATE OF	COMPLETIO	a: 3 July	1983	
Key Kopas: Hirsuitism, C	imetidine				
TITLE CF PROJECT: Pilot inv	estigation for the	treatme	ent of hirsu	itism with o	ral
cimetidine.					
PRINCIPAL INVESTIGATOR(S): Rob	ert A. Vigersky, M	.D., A11	an R. Glass	, M.D., Ira	Mehlman, MD
ASSOCIATE INVESTIGATOR(S): NO	ne				
FACILITY: HRAYC	DEPT/SVC: Kyle	Metabo]	ic Unit		
ACCURULATIVE PECCASE COST:	Accumulative Contract \$22,574	Cost: AccumuLative Supply C \$9,828.10			
FY-83 FEDCASE: CONTRACT COS \$10,000	T: SUPPLY COST: \$1,200	DATE OF ANNUAL P	COMMITTEE APPRI ROGRESS REPORT	CVAL 0F FEB 2 5 1983	1
STUDY USUSCIVE: To observe the mechanism of its effe	the effects of ciect.	metidin	in hirsuit	women and o	letermine
	for LH and FSH ove cimetidine 300 ml ditional four pati of the study on tatients, i.e. appr (TO DATE): 14	sr 8 hours 5 times ents have hese pat ox. 50%	rs, and a Tr daily. Hair re been stud tients has b decrease in	RH test before growth rate lied during to you and large hair growth F STUDY: 20	re and e is :his mirrored
Serious/Unexpected Side Effect None	S IN SUBJECTS PARTICIPA	ring in Pa	OJECT(IF NONE	:(ETATE CE	
CONCLUSIONS: Cimetidine is of the idiology. Its effrate of hair growth.	s a safe effective fects are reversab	treatme Le and t	nt of hirsu here is a 5	itism regard 0% decrease	less in the
PUBLICATIONS OR ABSTRACTS, FY-	82: None				-
Technical Approach (cimetidine by shavir	(continued): deng and weighing	termin a meas	ed before ured area	and while of hair g	on rowth.
Progress During FY-8 administered. A pro and spironolactone is waiting approval by	tocol for the a	dminis has be	tration o en applie	f cimetidi: d for and	n e

DATE: 8 Oct. 82 HORK UNIT IK	o.: 1311 - 79	STATUS	INTERIM X	FINAL
STARTING DATE: November 197	79 DATE OF	COMPLET	ion: 1-2 year	:s
KEY KORDS: Subacute thyroic	litis/biosynthetic	defect	·	
TITLE CF PROJECT: Assessment synthesis of thyroid hosthyroiditis (SAT)	of thursdid funct	ion and	the intrath	phases of subacute
PRINCIPAL INVESTIGATOR(S): ROL	pert C. Smallridge	LTC M	С	
ASSOCIATE INVESTIGATOR(S):L. I				N. Whorton, GS-11
FACILITY: NRAYC	DEPT/Svc: Medic			
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT	Созт:	ACCUMULATIVE	SUPPLY COST:
FY-83 FEDCASE: CONTRACT COS \$1,000.00	\$2,500.00			ROYAL_0= T FEB 2 5 1983
STUDY OBJECTIVE: To determine thetic exists in SAT, weither test may predict TECHNICAL APPROACH: Blood teuntil the disease resolution at end of study. PROGRESS DURING FY-82: Four name of the progress of th	hat the HLA type of the occurrence of sts and fluorescenves. A 3-hour RAI HLA typing is done we patients enroll	perman t scans U with in tis	ent hypothy are done e perchlorate sue typing	roidism very 4-6 weeks discharge is lab.
Murber of Subjects Studied:				
FY-82: 4 TOTAL	(TO DATE): 16	Befo	RE COMPLETION	of Study: 4 more
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPA	TING IN P	ROJECT(IF HONE	SO STATE):
CONCLUSIONS: Several patient defects. HLA typing da	nts have profound lata are presently	nypothy being a	roidism and nalyzed.	biosynthetic
PUBLICATIONS OR ABSTRACTS, FY-	82:			

DATE: 8 Oc. 82 HORK UNIT N	0.: 1313-79	STATUS: INTERIM X FIRE
STARTILE DATE: November 197	9 DATE OF	COMPLETION: Indefinite
Key Words: TSH/radioimmuno	assay	
Time of Project: A Radioimmunoassay	for Human TSH	
PRINCIPAL INVESTIGATOR(S): Rob		
ASSOCIATE INVESTIGATOR(S): R.C	Dimond, COL MC;	Nancy E. Whorton, GS-11
FACILITY: KRAYC	DEPT/Svc: Medic	cine/Metabolism
ACCUPARATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:
FY-83 IEDCASE: CONTRACT COS	T: SUPPLY COST: \$500.00	DATE OF COMMITTEE APPROVAL DE 25 1
STUDY OBJECTIVE: Ongoing nee		perthyroid subjects to maint
TECHNICAL APPROACH: Venipuno	ture	
PROGRESS DURING FY-82: Sera w	was obtained from t	two volunteers.
MUMBER OF SUBJECTS STUDIED:		
FY-82: 2 TOTAL	(TO DATE): 8	BEFORE COMPLETION OF STUDY: 2/3
SERIOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPAT	TING IN PROJECT(IF NONE SO STATE):
None		
CONCLUSIONS:		•
None expected		
PUBLICATIONS OR ABSTRACTS, FY-8	2:	
None		

DATE: 250ct82	HORK UNIT NO	.: 1314-79	STATUS	INTERIM X	Final			
STARTING DATE:		DATE	OF COMPLET	ION:				
Key Nords: Ipo	date/Thyro	d Function/Fast:	ng					
TITLE OF PROJECT:	Time of Project: Examination of the Effect of Ipodate (oragrafin) on Thyroid Function							
PRINCIPAL INVESTI	-	enneth D. Burman						
ASSOCIATE INVESTI	GATOR(S): RO	bert C. Smallrie			Dent of Physic			
FACILITY: HRAYC		DEPT/SVC: De	ot of Med	1/ KMU/ Endo:	Dept of Physio			
ACCUMULATIVE PEDC	ASE Cost:	ACCURULATIVE CONTRAC	T Cost:	ACCUMULATIVE	SUPPLY COST:			
FY-83 i'EDCASE:	CONTRACT COST	: Supply Cost:	DATE OF	COMMITTEE APPI PROGRESS REPOR	ROVAL OF FEB 25 1983			
STUDY COLECTIVE:	To determi	ne if Ipodate ad	ninistra	tion alters	TSH responses.			
TECHNICAL APPROACE and 13/14 Tev	_{H:} Ipodate i ēls are mea	s administered b sured.	oth in t	he fed and	fasting periods			
been determin	ed that Ipo	ximately 25 pati date inhibits in esponse to TRH i	ter-thyr	oidal and in				
HUMBER OF SUBJECT			··					
FY-82: 30	TOTAL	(TO DATE): 30	Befo	RE COMPLETION	о л Sтиру <u>: 40</u>			
SERIOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PARTICIP	ATHE IN P	ROJECT (IF NONE	SO STATE):			
None		• .						
CONCLUSIONS: Ipo in the pituita to TRH.	date alters ary and that	s extra thyroida : Ipodate decrea	converses TSH 1	sion, especi pasal levels	ally occurring and response			
	•							
PUBLICATIONS OR AS	STRACTS, FY-8	2: Manuscript su	bmitted	to the Jour	nal of Clinical			

Progress During FY-82 (continued): This effect of Ipodate is blocked by T3 administration.

								
DATE: 8 Oct 82	Hose Curr II	0.: 1315-80		STATUS:	PEXCENSI	Fire.		
STARTING DATE: 13 Nov 1979 DATE OF COMPLETION: 13 Nov 1982								
Key Hopps: Sex	Steroid Re	ceptors, Thy	mus					
TITLE OF PROJECT:	Sex Stero	id Receptors	in the	Mouse	Thymus			
		•		•				
PRINCIPAL INVESTI	gator(s): Ro	bert A. Vige	rsky, N	1.D.				
ASSCRIATE INVESTI	GATOR(S):							
FACILITY: WRANG		DEPT/SVC:	Kyle	Metabol	ic Unit			
Accumulative MEDC \$2850	ASE Cost:	Accumulativa (LATIVE CONTRACT COST: ACCUMULATIVE SUPPLY COST					
FY-83 FEDCASE:	CONTRACT COS	T: Supply Cost	r: -	DATE OF C	COMITTEE I	PERCYAL OF PER 2 5 1983		
STUDY OBJECTIVE:	See A	ttached						
TECHNICAL APPROAC	H: See A	ttached						
PROGRESS DURING F		ttached						
Number of Subject	s Studied: (
FY-82: Not Appl	. Total	(TO DATE):		_ Before	COMPLETIO	יאפטד2 גס ווכ :		
Serious/Unexpected Not Applicab	D Side Effects le	S IN SUBJECTS PA	RTICIPATI	ing in Pao	UECT(IF IN	DNE SO STATE):		
CONCLUSIONS: An nouse thymus and	androgen r d this may	eceptor def be linked t	ect may	be pre	sent in	the male NZB		

mouse model.

Publications on Abstracts, FY-82: Vigersky RA, Raveche ES, Tjio JH, and Steinburg A. "Murine Thymic Androgen Receptors II: Comparison of NZB to Normal Mice", Journal of Immunopharmacology, in press 1982

Work Unit No: 1315-80

Study Objective: To determine whether there are receptors for testosterone and estradiol in a mouse thymus gland.

Technical Approach: Normal and NZB mice are used to determine the presence or absence of cytosolic and nuclear receptors in their thymus gland. Thymucitu is homogenized and centrifuged and the cytosol is used in studies of binding of estradiol and dihydrotestosterone.

Progress During FY82: No further progress was made on this protocol during the past fiscal year.

DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-ME

Protocol #1315-80

to C, DCI

ROM Robert A. Vigersky, MD DATE 4 Feb 83

CMT 1

Dr. Vigersky/ecc/61793

- 1. We wish to keep this protocol active so that future studies can be expeditiously performed based on current work on techniques being developed at this time.
- 2. No budget is requested for FY 83.

ROBERT A.

VIGERSKY, M.D.

LTC, MC

Assistant Chief, Endocrine-Metabolic Service

DATE: 250ct82	HORK UNIT NO.	: 1316-80	STATUS:	INTERIM X	Firm	
STARTING DATE:		DATE (F COMPLETI	0:1:		
KEY NORDS:						
TITLE OF PROJECT:	T3 Recepto	ors in Human Whi	te Cells	and Liver		
· · · · · · · · · · · · · · · · · · ·						
PRINCIPAL INVESTIG		nneth D. Burman,				
ASSOCIATE INVESTIG	Dav: SATOR(s): Lati	id Peura, LTC, M nam, PhD., Yin-Y	C, Leona ing Niub	rd Wartofsky	, COL, MC, Ke	eith
FACILITY: WRANC				d/Endo/KMU/D	CI/GI	
ACCUMULATIVE PEOC	SE Cost:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE S	SUPPLY COST:	
FY-83 PEDCASE:	CONTRACT COST:	SUPPLY COST:	DATE OF ANNUAL P	COMMITTEE APPROPRIES REPORT	WAL OF FEB 2.5 1983	
preparations, assessment in TECHNICAL APPROACE	and membrane white cells !: Nuclear	and membrane rec	nd to se eptors a	re siolated	by ultracent:	rifugation
techniques and the placement		e labelled T3 or performed.	14 15 a	daea to thes	se preparation	ns and
PROGRESS DURING FY results indica	<u>/-82</u> : Three te that the	patients have be binding is simi	en studi lar to t	ed and the phat obtained	reliminary I in earlier	
studied of per		te cerrs.	· —			
FY-82 <u>: 5</u>	TOTAL (TO DATE): 5	Befor	E COMPLETION OF	Sтиру: 15	
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE):						
None Conclusions: T3	receptors e	xsist in the thy	roid gla	ınd.		
	•	-				
PUBLICATIONS OR AR	STRACTS, FY-82	None yet.				

DATE: 8 Oct 82 Hose Unit flo	a.: 1317 - 80	STATUS: IN	TERIM	Firm X
STARTING DATE: 11 December	1979 DATE OF	COMPLETION:	1 Octobe	r 1982
KEY NOODS: Hirsuitism, Ada	renal, Androgen			
TITLE OF PROJECT: Investigat	tions of the Idiol	ogy of Idio	pathic Hir	suitism
PRINCIPAL INVESTIGATOR(S): RO	bert A. Vigersky,	M.D.		
ASSOCIATE INVESTIGATOR(S): FACILITY: NRAYC	Drar/Syr:		77 - 14	
	DEPT/S/C: Kyle			
ACCURRATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT 5800		WULATIVE SUP	
FY-83 FEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMM ANNUAL PROSE	ittee <i>R</i> eprova ess Report _	(L 0;
genesis. This would perm dexamethasone suppression <u>Technical Approach</u> : Infu ACTH measurement of adren	of the pituitary sion of ACTH over	adrenal axi 24 hours wi	is. ith free- a	
Progress During FY82: No	further progress	in this pro	otocol has	been made.
	(TO DATE): 10			
SERIOUS/UNEXPECTED SIDE EFFECT None	s in Subjects Participal	ing in Projec	T(IF NONE SO	STATE):
CONCLUSIONS: Few if any partial congential adrenal hyper	tients with idiopa erplasia.	thic hirsui	tism have	mild forms
PUBLICATIONS OR ABSTRACTS, FY-	32: None			

							
DATE: 250ct82	HORK UNET NO.:	1319-80	STATUS:	INTERIM	X FIRM	_ _	
STARTING DATE: May 1980 DATE OF COMPLETION: May 1984							
KEY KORDS: Cyst	tic Mass/Thyro	id Gland/Thyroi	d Hormo	ne.	·		
TITLE OF PROJECT:		Hormone Admini in the Thyroid		on Decrea	se the Siz	e of	
PRINCIPAL INVESTI	CATORION	eth D. Burman,					
ASSOCIATE INVESTI	GATCR(s): Robert	C. Smallirdge,	LTC, N	1C	 -		
FACILITY: MRAYO		DEPT/Svc: Dept	of Med/	/Endo/KMU	/Dept of P	hysio WRAIR	
Accumulative iEOC	1	CUMULATIVE CONTRACT	Cost:	ACCUMULATI	IVE SUPPLY CO	ST:	
FY-83 I'EDCASE:	CONTRACT COST:	SUPPLY COST:	Date of Annual P	COMMITTEE / PROGRESS REP	PPROVAL OF PORT FEB 25	1983	
the effects of	cysts develor	whether thyroicoment in the thy	roid g	land.			
hormone or not	and sonogram	re randomly allo evaluation of v	whether	the thyr	old cyst a	iterea.	
PROGRESS DURING F study and it a increasing res	ppears that th	mately 10 patier nyroid hormone 1 ts.	its have thus fa	e been in r makes n	i cluded in o differen	this ce in	
Number of Subjects							
FY-82: 10	TOTAL (TO	DATE): 15	Befor	E COMPLETIO	אָכּעד פֿר אָס אָכ <u>:</u>	30	
None		SUBJECTS PARTICIPAT		•			
CONCLUSIONS: Premake any diffe	liminary studerence in influ	ies indicate the uencing the res	at thyr olution	oid hormo	one does no S.	 [
PUBLICATIONS OR A	BSTRACTS, FY-82:	None yet.		<u> </u>			

DATE: 250ct82 Hook Unit N	o.: 1320-80	STATUS: INTERIM X FIRM				
STARTING DATE: 1 January 1981 DATE OF COMPLETION: 1 January 1984						
KEY MORDS: Cyclic AMP/G1	ucagon					
TITLE OF PROJECT: Cyclic	AMP Response to Glu	cagon				
PRINCIPAL INVESTIGATOR(S):	Kenneth D. Burman,		_			
ASSOCIATE INVESTIGATOR(S): H.	Linton Wray, COL,	MC, Vincent Butler				
FACILITY: WRANC	DEPT/SVC: K	MU				
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT C	OST: ACCUMULATIVE SUPPLY COST:				
		DATE OF COMMITTEE PPPROVAL OF ANNUAL PROGRESS REPORT FEB 2.5.1				
STUDY USJECTIVE: To ascerta response to glucagon is	in if during the fa	sting state in humans cyclic	E AMP			
measured as formed by th	ne kidney and excret	es of 1-3 ng/Kg/min and cycliced in the urine. Cyclic AMP and glucagon is noted to inc	measurement			
PROGRESS DURING FY-82: Pre1	iminary work has be	en done to optimize the assa				
cyclic AMP and thyronine	hormones. No subj	ects have been studied yet.				
Munser of Subjects Studied:						
FY-82: TOTAL	(TO DATE):	BEFORE COMPLETION OF STUDY: 20				
SERIOUS/UNEXPECTED SIDE EFFECT None	S IN SUBJECTS PARTICIPATI	NG IN PROJECT(IF NONE SO STATE):				
CONCLUSIONS: None yet.						
PUBLICATIONS OR ABSTRACTS. FY-	82: None yet.					
Technical Approach:	continued					
this response. The	question of thi	s study is whether the				
response is decreas	ed in fasting pa	tients.				

					
DATE: 250ct82	HORK UNIT NO .:	1321-80	STATUS	: INTERIM X	Fire
STARTING DATE:		DATE	OF COMPLET	10n:	
	SH/Physiologic	States		·	
TITLE OF PROJECT:	TSH Recepto	rs in Physiolo	gic Sta	tes	
PRINCIPAL INVESTI	GATGR(s): Kenn	eth D. Burman,	LTC, M		
ASSOCIATE INVESTI	GATOR(S): Yvon	ne Lukes, Robe	rt C. Si	mallridge, LT	rc, Mc
FACILITY: WRANC		DEPT/SVC: DE	pt of M	ed/Endo/KMU/C	CI
Accumulative PEDC 3,000.		CUPULATIVE CONTRAC	τ Cosτ:	ACCUMULATIVE S	SUPPLY COST:
FY-83 PEDCASE:	CONTRACT COST:	SUPPLY COST:	DATE OF ANNUAL	COMMITTEE APPROPRIES REPORT	OVAL OF FEB 2 5 1983
Study Osjective: in diebates an	To determine de fasting.	if TSH recepto	rs in t	hyroid gland	are altered
TECHNICAL APPROAG diabetic or fa					ave been rendered e fed period.
levels decreas	se in fasting ease is not as	and diabetes a	ind that	the receptor	evealed that TSH r levels increase roidal cyclicAMP.
FY-82 <u>:</u>	TOTAL (TO	DATE):	Befor	RE COMPLETION OF	: STUDY:
SER LOUS/UNEXPECTED	SIDE EFFECTS IN	SUBJECTS PARTICIPA	ATING IN P	ROJECT(IF NONE S	O STATE):
CONCLUSIONS: TSF	l regulates it	's own receptor	or.		
PUBLICATIONS OR AB	STRACTS, FY-82:	None yet.			

DATE: 250ct82 1/0	AK CHIT NO.	: 1322-80	STATUS	INTERIM X	Fina_
STARTING DATE: 1 A	ugust 19	80 D.	TE OF COMPLET	ion: 1 Augu	ıst 1983
Key Nords: Calcit	onin/Nit	roprusside/T3			
TITLE OF PROJECT: T	he Relat	ionship Betwe	en Calcito	nin, Nitropro	usside and T3.
PRINCIPAL INVESTIGATO		nneth D. Burm	an, LTC, M		
ASSCRIATE INVESTIGATO	g(s): Pn	yllis Kesler	VIAI		
FACILITY: VRAYE		DEPT/SVC:	KMU		~
Accumulative MEDCASE	Cost:	ACCUMULATIVE CONT	RACT COST:	ACCUMULATIVE	SUPPLY COST:
FY-83 PEDCASE: CON	TRACT COST:	Supply Cost:	DATE OF ANNUAL	COMMITTEE APPRI PROGRESS REPORT	OVAL OF FEB 2 5 1988
STUDY USJECTIVE: To conversion of T4		ne if calcito	nin and mi	troprusside	inhibit thyroidal
TECHNICAL APPROACH: thyroxine and the					d with unlabelled pimmunoassay.
PROGRESS DURING FY-82 specifically calc T4 to T3 as was h	itonin a	nd nitropruss			
MUMBER OF SUBJECTS STU					
FY-82 <u>:</u>	TOTAL (TO DATE):	Befor	RE COMPLETION OF	= Study:
SERIOUS/UNEXPECTED SIG	DE EFFECTS	IN SUBJECTS PARTI	CIPATING IN P	ROJECT(IF MONE S	SO STATE):
CONCLUSIONS: Nitro	prusside	and calciton	in do not	inhibit T4 to	o T3 conversion.
PUBLICATIONS OR ABSTRA	acts, FY-87	·	·		
, , , , , , , , , , , , , , , , , , , ,		•			

					_
DATE: 250ct82	Mark Unit No.:	1323-80	STATUS	S: INTERIN X	Frat
STARTING DATE:	August 1980	DATE O	F COMPLET	rion: August	1983
KEY HORDS: TSH/F	Receptors			·	
TITLE OF PROJECT:	TSH Recepto	ors in Human Tis	sues		
PRINCIPAL INVESTIG		neth D. Burman			
ASSOCIATE INVESTIG	Yvon	ne Lukes, Harol scher, Richard			
FACILITY: WRAYC				Surgery	2
ACCUMULATIVE PEDCA	SE Cost: Ac	CUHULATIVE CONTRACT	Cost:	ACCUMULATIVE S	UPPLY COST:
FY-83 MEDCASE:	CONTRACT COST:	SUPPLY COST:	DATE OF	COMMITTEE APPROPRIOR	VAL 0F FEB 2 5 1983
and normal tiss proteins in Granteins in Gra	sue, (2) to unives' dx, has: (a) α, β, hase percent of (b) radio respectively. (b) radio respectively.	cells that are receptor technic echniques have to e to determine	s to models. (3) sor cell e specie que of been de beta r	easure thyroic) to measure; l antibodies fic variants TSH binding u veloped and w eceptors are	d stimulation and compare used to determine
MUMBER OF SUBJECTS	בוסטונם:		<u> </u>		
FY-82: 5	TOTAL (TO	DATE): 10	Befo	RE COMPLETION OF	Sтиру: 30-40
SERIOUS/UNEXPECTED	SIDE EFFECTS IN	SUBJECTS PARTICIPAL	ring in P	ROUECT(IF NONE SO	STATE):
None				•	
CONCLUSIONS: (1) TSI displaces b infiltrated wit	inding of TS	H and beta rece	ptors,	(3) thyroid g	glands are
PUBLICATIONS OR ABS	TRACTS, FY-82:	None			

Work Unit #1323-80

Study Objective Cont'd:

 α and β cell levels and function in peripheral blood and glands of n/s, Graves', hashimoto's, cancer, and other thyroid diseases, (4) use hybridoma antibodies against Graves' proteins and TSH receptor probes in ascertaining thyroid antigens relationships.

Technical Approach Cont'd:

effect of α and β cells and their interrelationship in normals, Graves', etc., (e) thyroid membranes also to be used for beta and alpha receptor memner, (f) IgG and TSH receptor hybridomas antibodies to be used to ascertain effect of A $^+$ E.

Progress During FY-82 Cont'd:

immunoglobulin may displaced these binding cites.

DATE: 15 Sep82	HORK BUIT NO .:	1324-80	STATUS:	INTERIM X	Fire	
STARTILES DATE: N/A DATE OF COMPLETION: N/A						
KEY KORDS: Clor	nidine, catec	holamines, pheoc	hromocy	toma		
TITLE OF PROJECT:	Suppression	on of plasma cat	echolam	nines by clon	idine	
PRINCIPAL INVESTIG		n Glass MS LTC M				
ASSOCIATE INVESTIG	GATOR(S): Kris	ten Raines MD CP				
FACILITY: HRAYC		DEPT/Syc: Endoc	rinolog	y-Metabolism	1	
Accumulative #EDC/	ISE Cost: Ac	CUMULATIVE CONTRACT (O	Cost:	ACCUMULATIVE S	PPLY COST:	
FY-83 I'EDCASE:	CONTRACT COST: 2,000	SUPPLY COST: 4,000	DATE OF ANNUAL P	COMMITTEE APPROPRICES REPORT	VAL OF FEB 2.5 1983	
diagnosing ear	ly pheochromo !: Measuremen	he clonidine sup cytoma t of plasma cate				
	y other inves from Johns H	cts studied. Ori tigators. Revise opkins.	ed proto	ocol not star	rted pending	
FY-82: 4	TOTAL (TO	DATE): 4	_ Before	E COMPLETION OF	STUDY: 20	
Serious/Unexpected Moderate hypot	Side Effects in ension in 2 s	Subjects Participation	ng in Par Lonidin	OUECT(17 NOME SO	STATE):	
with pheochrom	ocytoma- our ta recently p	ot suppress plas results in a ver published by othe	y smal	l number of s	subjects	
PUBLICATIONS OR AB	STRACTS, FY-82:					

DATE: 210ct82 HOSK UNIT !	io.: 1325-80	STATUS: INTERIM X FIRM
START 1:5 DATE: May 1981	DATE OF	OF COMPLETION:
KEY NORDS: Thyroid/Acety	lase	
	Acetylase Activity	y and Thyroid Hormone Receptors
PRINCIPAL INVESTIGATOR(S):	Kenneth D. Burman.	LTC, MC
ASSOCIATE INVESTIGATOR(S):	William B. Fears, M	MAJ, MC, Keith Lathan, Ph. D.
FACILITY: WRAYE	DEPT/SVC:	
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	r Cost: ACCUMULATIVE SUPPLY COST:
FY-83 i EDCASE: CONTRACT COS	ST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983
Study OBJECTIVE: To determine thyroid hormone administ		activity in rats is altered by
for periods of approximate and the amount of acety	ately 2 weeks and l lase activity deter	T4 were administered to rats liver and white cells are isola rmined by radiolabel.
PROGRESS DURING FY-82: Stud: indicate that T3 admini:	ies have been compl stration does incre	leted and the preliminary resulterest the ease thyroid hormone action.
Murser of Subjects Studied:	Rat Study	
FY-82: TOTAL	(TO DATE):	BEFORE COMPLETION OF STUDY:
None	•	ATING IN PROJECT(IF NONE SO STATE):
Conclusions: T3 increases	acetylase activity	у.

Publications on Abstracts, FY-82: Abstract, American Thyroid Association, 1981

DATE: 250ct82	HORK UNIT No.: 1326-8	STATU	S: INTERIM X	Final
STARTING DATE:	l December 1981	DATE OF COMPLE	TION: 1 Decembe	er 1984
Key Horos: Nib	oling/Gorging			· · · · · · · · · · · · · · · · · · ·
TITLE OF PROJECT:	Nibbling vs Gorgin	ng		
PRINCIPAL INVESTI		Burman, LTC, M		
ASSOCIATE INVESTI	Robert C. Sm GATOR(S): Wolf Pinks	nallridge, LTC <u>ITC MC Dawn</u>	, MC, Leonard Carlson, MAI,	Wartofsky, COL, MC
FACILITY: NRANC	DEPT/SV			
ACCUMULATIVE PEDC 3,000.00	SE Cost: Accumulative	CONTRACT COST:	ACCUMULATIVE S	UPPLY COST:
FY-83 PEDCASE:	CONTRACT COST: SUPPLY CO	DATE O	F COMMITTEE APPRO PROGRESS REPORT	VAL 07 FES 25 1993
STUDY OBJECTIVE: in different p	To determine if eat: roportions causes di	ing the same a fference in fu	mount of calor el substrates	ries per day
either with on	: Patients are random e meal per day or div time of the meal in	vided into thr	ee or four mea	als oer day. In
PROGRESS DURING F	<u>/-82</u> :			
MUMBER OF SUBJECTS	S STUDIED:			
FY-82:	TOTAL (TO DATE):	Ber-	ORE COMPLETION OF	Sтиру <u>:</u>
SERIOUS/UNEXPECTED	SIDE EFFECTS IN SUBJECTS	PARTICIPATING IN	PROJECT (IF HONE S	STATE):
CONCLUSIONS:				
	•			
PUBLICATIONS OR A	STRACTS. FY-82:			
Technical Ap	proach Continued	function	tests and	metabolic
substrates a	re measured.			

DATE: 8 Oct 82 Hook User No	: 1327-81	STATUS: INTERIM X FIRE	
STARTILS DATE: 10 July 198	1 DATE OF C	ON-LETICH: 10 July 1984	
Key logs: Sex Steroid Rec	eptors, lymphocytes	3	
TITLE CF PROJECT: Sex Stero	id Hormone Receptor	s in Human Lymphocytes	
PRINCIPAL INVESTIGATOR(S): RO	bert A. Vigersky, M	i.D., Jeffrey L. Berenberg, Jimmy	Light
ASSOCIATE INVESTIGATOR(S): Dav	id Poplack, MD, Jul	ie Blatt (at NIH)	
FACILITY: MRAYE	DEPT/S/C: Kyle Me	etabolic Unit + Transplantation S	vc
ACCURALATIVE MEDICASE COST: \$5162	Accumulative Contract Co	OST: ACCUMULATIVE SUPPLY COST:	
FY-83 PECCASE: CONTRACT COST 0 \$3,000	r: Supply Cost: [DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983	
Study OBJECTIVE: See Att	ached		
TECHNICAL APPROACH: See Att	ached		
PROSESS DURING FY-82: See Att	ached		
Number of Subjects Studied:			
FY-82: 15 TOTAL	(TO DATE): 25	BEFORE COMPLETION OF STUDY: 120	
Serious/Unexpected Side Effects	S IN SUBJECTS PARTICIPATI	NG IN PROJECT(IF NONE SO STATE):	
Conclusions: Androgen rece	ptors and detectabl	e and quantifiable in the lympho	cytes

<u>CONCLUSIONS</u>: Androgen receptors and detectable and quantifiable in the lymphocytes of normal men but not normal women and estrogen receptors are detectable and quantifiable in the lymphocytes and normal women but not normal men. The quantity and affinity of receptors for the sex steroids appears to be the same in men with a variety of endocrine disorders.

PUBLICATIONS OR ASSTRACTS. FY-S2:1. Vigersky, RA, Rick MK, Cole D, Shohet R, Light J, and Poplack D. "Androgen Receptors in Human Peripheral Lymphocytes", Journal of Clinical Endocrinology and Metabolism, in press. 2) Vigersky R, Rice M, Cole D, Shohet R, and Poplack D., "Estrogen Receptors in Human Peripheral Lymphocytes", Clinical Research 30:278A, 1982.

Work Unit No: 1327-81

Study Objective: To detect, quantitate and characterize receptors for estrogen and androgens in the lymphocytes in normal men and women and in the lymphocytes of individuals with various endocrine and renal and neoplastic disorders.

Technical Approach: Leukaphoresis using either a manual approach or by the automated blood cell separaters are used in all patients except those with renal failure. The latter undergoing thorasic drainage will have their lymphocytes obtained from that source. Cytosol made from the lymphocytes is used for binding studies.

Progress During FY82: A modification of the prior technical approach has allowed us to look at both cytoplasmic and nuclear receptors in the same cells. This has a great advantage in detecting the relative location of the receptors which could previously not be determined. Several patients with a variety of disorders have been studied and comparison of results of some of these with the classic fibroblasts receptor assay for androgen has been achieved through the cooperation of Dr. Charles Eil at NNMC.

DATE: 10-21-82 HORK UNIT NO	.: 1328-81	STATUS: INTERIM X	Fire
STARTING DATE: August 1981	DATE OF	COMPLETION: August 1	983
KEY KORDS: Prolactin;	aging		
Title of Project: In vivo rat.	prolactin (PRL) in	the young and agi	ng female
PRINCIPAL INVESTIGATOR(S): Rob	ert A. Vigersky, M	.D.; Judith E. Bea	ch, Ph. D.
ASSOCIATE INVESTIGATOR(S): no	ne		
FACILITY: NRAYC	DEPT/Svc: Kyle	Metabolic Unit	
Accumulative PEDCASE Cost:	Accurulative Contract (Cost: AccumuLative S \$7095.5	
FY-83 FEDCASE: Contract Cost	: Supply Cost:	DATE OF COMMITTEE APPROACH ANNUAL PROGRESS REPORT	FEB 2 5 1983
STUDY OBJECTIVE: To increase mediates the inhibitory a			
TECHNICAL APPROACH: Spontaneo LH and blood withdrawn vi These will be compared to	a a chronic atrial	catheter for meas	urement of prolactin.
PROGRESS DURING FY-82: All rapersistent estrus rats whiled at 3 hour intervals	dioimmunoassays es ere chronically ca	tablished. Severa	al (15)spontaneous ted with LH and
MUMBER OF SUBJECTS STUDIED:	INVEL AL TEASE 5 W	A TO A THE TRU AS	below)*
FY-82: 40 TOTAL	(TO DATE): 40	BEFORE COMPLETION OF	: STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS none	IN SUBJECTS PARTICIPAT	ING IN PROJECT(IF HONE S	O STATE):

CONCLUSIONS: Insufficient numbers of animals have been completed to statistically evaluate the results at present. However, initial data from these persistent estrus rats (at least 6 months old) suggest that absolute levels of prolactin as well as the semicircadian rhythmicity of this hormone is important for the temporary resumption of cycles, the manifestation of pseudopregnancy, or the continuation of persistent estrus as a result of the LH injection.

Publications or Abstracts. FY-82:
Beach, J.E., L. Tyrey, D. Schomberg and J.W. Everett. Mocturnal and diurnal prolactin, LH, FSH, estrogens and progesterone in spontaneously persistent estrous rats. Abstract presented at ACE Meetings in New York City, September, 1981. Manuscript submitted for publication to AGE.

* LH assays are in progress and additional rats are allowing to "age" for the remainder of the study.

DATE: 10-20-82 HORK UNIT N	o.: 1329 - 81	STATUS: INTERIM X FIRE			
STARTING DATE: August 1981 DATE OF COMPLETION: August 1983					
Key Nords: Prolactin; Aging					
		dispersed anterior pituitary			
cells in culture and the	effect of aging on	this secretion.			
PRINCIPAL INVESTIGATOR(S): RO	bert A. Vigersky. !!	.D.: Judith E. Beach, Ph. D.			
ASSOCIATE INVESTIGATOR(S):	none				
FACILITY: WRANG	DEPT/SVC: Kyl	e Metabolic Unit			
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT C	OST: ACCUMULATIVE SUPPLY COST:			
none	none	\$15061.28			
FY-83 FECCASE: CONTRACT COS	T: Supply Cost: 6700	DATE OF COMMITTEE APPROVAL OF 2 5 1933 ANNUAL PROGRESS REPORT FEB 2 5 1933	3		
Study OBJECTIVE: To increde dopamine controls prola	ease the inderstand	ing of the mechanism by which the anterior pituitary and ef	ifect of		
TEC NICAL APPROACH: Primary	cell cultures of r	at pituitary cells will be			
		of the animal (state of estrunding of dopamine agonists and			
		pamine receptor (from young and			
		d. Monolayer and superfusion			
culture techniques for p Muyser of Susuecus Studied:	ituitary cells have	been perfected. (continued b	elow)*		
FY-82: 80 TOTAL	(TO DATE): 80	BEFORE COMPLETION OF STUDY: 300			
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPATI	ING IN PROJECT(IF HONE SO STATE):			
		. none			
consistent with establis	hed results for sta				
	CT 1				

* Normal secretion of LH, FSH and prolactin as well as secretagogue response from pituitary cells from young female rats were determined in these systems for comparison with hormonal levels from cells from aging animals.

PUBLICATIONS OR ABSTRACTS. FY-82:

DATE: 20 Oct 82 HOPK UNIT N	o.: 1330-81	STATUS: INTERIN X FIRM			
STARTING DATE: 1 Oct 82 DATE OF COMPLETION: 1 Oct 85					
Key Koros: Thyroid/Hybro	doma	·			
	tion of Hybridoma f Thyroid Hormone	Antibodies as a Physiologic and TSH Action			
PRINCIPAL INVESTIGATOR(S): K	enneth D. Burman,	LTC, MC			
ASSOCIATE INVESTIGATOR(S):	···				
FACILITY: WRANC	DEPT/SVC:				
ACCUMULATIVE MEDICASE COST: 6,000.00	Accumulative Compract 58,304.00	COST: ACCUMULATIVE SUPPLY COST: 58,678.80			
FY-83 PEDCASE: CONTRACT COST	T: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 25 1983			
		73 receptor, TSI, and TSH receptor and complicated procedure involvi			
the fusion and making of	hybridoma cells a	and culturing out these cells and	6		
Processe Busine EV-S2. In Ja		ked with the WRAIR Hybridoma Labor	ratori		
and were successful in m	aking antibodies a	against TSH receptor. However, te	ech-		
	their routine use	and we are repreforming these st	tudie:		
MUMBER OF SUBJECTS STUDIED:	. Name				
FY-82: None TOTAL	(TO DATE): None	BEFORE COMPLETION OF STUDY:			
SERIOUS/UNEXPECTED SIDE EFFECTS	IN SUBJECTS PARTICIPAT	TING IN PROJECT(IF HONE SO STATE):			
None		·			
CONCLUSIONS: None yet.					
•					
PUBLICATIONS OF ABSTRACTS, FY-8	2: None				

DATE: 250ct82	HORK UNIT NO	: 1331-81	STATUS	: INTERIM X FIRM		
STARTING DATE:	1 August 19	81 DA	TE OF COMPLET	ICN: 1 August 1984		
Key News: TSH/TRH/Metoclopramide/Fasting						
TITLE OF PROJECT:	The Effective During F		ramide on	TSH Response to TRH		
PRINCIPAL INVESTI	02110111011	Kenneth D. Bur				
ASSOCIATE INVESTI	GATOR(S): Rob			MC, Phyllis Kesler		
FACILITY: WRANC		DEPT/Syc:	KMU/DCI/D	oiv pf Physio		
Accumulative PEDO	ASE Cost:	ACCUMULATIVE CONT		ACCUMULATIVE SUPPLY COST: 1,921.85		
FY-83 PEDCASE:	CONTRACT COST	: SUPPLY COST:	DATE OF FINNUAL	COMMITTEE APPROVAL OF PROGRESS REPORT PED 2 5 1983		
Study Osuscrive: of TSH during			e antigoni	ist will alter prolactin		
days and faste	d for appro	ximately 10 da	ys. Metod	maintaining diet for 5 clopramide is administered two periods and compared		
PROGRESS DURING F	Y-82: Approx	imately 25 pa	tients wer	e studied and it is concluded		
Metoclopramide	s been no ch e and that f	ange in prolactions	tin/TSH realist alter pro	esponse with or without olactin levels but does		
Number of Subject	s Studied:					
FY-82: 30	TOTAL (TO DATE): 30	ВЕГО	RE COMPLETION OF STUDY: 35		
Serious/Unexpecte	D SIDE EFFECTS	IN SUBJECTS PARTI	CIPATING IN P	ROJECT(IF NONE SO STATE):		
CONCLUSIONS: I period differ				rolactin in the fasting		
	·		 -			
PUBLICATIONS OR A	BSTRACTS, F1-82	: :				
Technical App	roach Cont'd	<u>l</u> :				
with placibo	administrati	on.				
Progress Duri	ng FY-82 Con	it'd:				
alter TSH leve	els as they	decrease duri	ng fasting	•		

DATE: 15 Sep 82	VOSK LIVET B	o.: 1332-82		STATUS:	Intering X	First
STARTING DATE: N	/ A		DATE OF	COMPLETI	0:1: N/A	
KEY HOPES: cano	er, adrena	l insufficie	ncy			
TITLE OF PROJECT:	Limitatio	n of Adrenal	Reserv	ve in Pa	tients with	Malignancy.
PRINCIPAL INVESTIG	PATGR(s): Al	lan Glass M	LTC M	С		
ASSOCIATE INVESTIG	-					
FACILITY: WRANC		DEPT/SVC	: Endo	crinolo	gy-Metabolis	sm
ACCUMULATIVE PECCA	SE Cost:	ACCUMULATIVE	CONTRACT	Cost:	ACCUMULATIVE	SUPPLY COST:
0		0			<u>. ο</u>	
FY-83 FEDCASE:	11,000			DATE OF P	COMMITTES APPR ROGRESS REPORT	OVAL 0F FEB 2 5 198
STUDY OBJECTIVE:	To evalua	ate the stat	us of a	drenal	function in	patients
	with cand	cer.				
TECHNICAL APPROACH	: Performa maligna	ance of shor	t ACTH	tests 1	n patients v	vien —
						
PROGRESS DURING FY	-82: Appr	oximately 15	patien	ts stud	ied, No data	a calculated
or assays run		patients ar	e combr	etea.		
Mumber of Subjects	Sಕರಾಚಾ:	1	5			100
FY-82: 15	Total	(TO DATE):	. 	Before	E COMPLETION OF	
SERIOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PA	RTICIPAL	ms in Pa	DJECT (IF HONE	SO STATE):
None						****
Concrastons:	Deferred-i	nsufficient	data			
PUBLICATIONS OR AB	STRACTS. FY-8	2:	-			
None						

DATE: 140ct82 Now Unit No.: 1333-82	STATUS: INTERIN X FIRM
STARTING DATE: 1 October 1981 DATE OF	Commetten: 1 October 1985
KEY LORDS: Thyroid Function, Critical Illne	ess
TITLE OF PROJECT: Thyroid Function in Cirit	cal Illness
PRINCIPAL INVESTIGATOR(S): K.D. Burman, LTC, MC	2
ASSOCIATE INVESTIGATOR(S): Jim Bombenger	
FACILITY: MRANC DEPT/Suc: Endo	ocrine/Medicine/Pulmonary Endocrine
Accumulative FEBCASE Cost: Accumulative Contract	COST: ACCUMULATIVE SUPPLY COST: 680.12
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMETTEE APPROVAL OF ANNUAL PROGRESS REPORT FED 2 0 1033
STUDY DELECTIVE: To determine what routine the determine what T3 receptors are in the cir-	
TECHNICAL APPROACH: Radioimmunoassay of serum of white cells and measurement of T3 and T4	T3, T4, rT3, TSH, and isolation
PROGRESS DURING FY-82: Approximately 15 patient and we have studied the white cell receptor solubilized and nonsolubilized techniques.	rs in two different ways utilizing
Hurses of Subjects Studied:	
FY-82: 15 TOTAL (TO DATE): 25	BEFORE COMPLETION OF STUDY: 50
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPAT	THE IN PROJECT(IF HOME SO STATE):
None	
CONCLUSIONS: Radioimmunoassay pf serum T3, To white cells and measurement of T3 and T4 re	4, rT3, TSH, and isolation of the ecceptors in peripheral lymphocytes.
· .	
Publications on Abstracts, FY-82: Presentation a Meeting, 1981, paper being written concern	t the American Thyroid Association ing newer results.

Progress During FY-82 Cont'd:

a critical illness may have a decreased receptor binding and certainly always have decreased serum T3 and most of the time serum T4 and that TSH may not be an accurate measure of the disease process.

DATE: 29 Sep 82 Now UNIT IN	o.: 1334 - 82	Status	: Interior x	_ <u> </u>	
STARTING DATE: September 1982 DATE OF COMPLETION: Spring 1983					
Key Moras: Nutritional	assessment				
TITLE OF PROJECT: Dietary		rition	nal Status	As ses sment	
in Endocrine Disorder	rs 			~ ~~ ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
PRINCIPAL INVESTIGATOR(S): ME	AJ Dawn E. Carls	on			
ASSOCIATE INVESTIGATOR(S): NO	one				
FACILITY: NRAYE	DEPT/Syc: Endo	crine	<u>Metabolic</u>	Service	
ACCUMPLATIVE PEGCASE COST:	Accumulative Contract O	Cosr:	ACCUMULATIVE . 0	Supply Cost:	
FY-83 PEDCASE: CONTRACT COS	T: Supply Cost:	DATE OF FRANCE	Committee Name Progress Report	FEB 2 5 1983	
STUDY OBJECTIVE: To determents admitted to TECHNICAL APPROACH: Patien and diet history for gator to determine no	o the Endocrine ts will complete m. Data will be utritional adequ	Servie a nu e evaluacy o	ce tritional uated by p f diet con	risk questions rincipal inves sumed by pation	ent.
Prosess Duains FY-82: Form written and approved	s and analysis, and data coll	tool w ection	ere develo was initi	ped, protocol ated.	was
Nursex of Suscects Studied:			<u> </u>		
	(TO DATE): 4		RE COMPLETION O		
Sarious/Unexpectab Side Effect No serious/unexpect			BINCH 31)TOBLOS	SO STATE):	
Conclusions: Not applic	able	•			
,					
·					
PUBLICATIONS OR ABSTRACTS. FY-	\$2:				
None					

			-			
DATE: 15 Sept 82 Now Unit Il	0.:1335-82	SIATUS	i latenin >	K Fros		
STARTICE DATE: N/A	DATE OF	CONTET	10:1: N/A			
Key Novos: nifedipine, p	ituitary,		· · · · · · · · · · · · · · · · · · ·			
TITLE OF PROJECT: Effect of Calcium Channel Blockers on Pituitary Testicular Function.						
FRISCIPAL INVESTIGATORISS.	llan Glass MD LTC					
ASSOCIATE INVESTIGATOR(S): A	nthony Zavadil MD					
FACILITY: KRAYE	DEPT/Syc: Endo	crinolo	gy-Metabol:	ism		
Accumulative MEDCASE Cost: 0	ACCUMULATIVE CONTRACT 0			0		
FY-83 NEDCASE: CONTRACT COST		DATE OF EMMUAL	Committee AP PROGRESS REPO	PEROVAL OF DRT FEB 2.5 1929		
STUDY DESIGNATIVE: To evalua	te the effect of n	ifedipi	ne on pitu	itary function		
TECHNICAL APPROACH: Perform patients are started on	nifedipine					
PROGRESS DURING FY-82: One p temporarily halted due to resume in FY 83.	patient studied pre departure of card	-nifedi iology	pine. Furt co-investi	her progress gator. Will		
Munaea of Subjects Studied:						
	(TO DATE): 1					
Serious/Unexpected Side Effects None	s in Subjects Participat	ing in P	ROJECT(IF NON	E SO STATE):		
ComcLU31003: Deferred-inst	ifficient data					
Publications or Abstracts. FY-8	32:					
None						

DATE: 18 Oct 82 Hask User Al	1336-82	STATUS: INTE	RIN X First	<u> </u>		
STARTING DATE: March 198	DATE OF	COMPLETIC:1:	March 1984			
KEY KORDS: Development Ant				~ 		
TITLE OF PROJECT: Development of an Antisera and a Radioimmunoassay (RIA) Procedure for the Analysis of 10,25-Dihydroxycalciferol						
PRINCIPAL INVESTIGATOR(S):	Joseph Bruton, Ph.	D.				
ASSOCIATE INVESTIGATOR(S): H.	Linton Wray, Ethel	bert Dawson	and Vincent	Butler		
FACILITY: MRAYC	DEPT/SVC: DCI	/ KMU				
Accumulative PEDCASE Cost: None	Accumulative Contract (None	lost: Accum	ULATIVE SUPPLY .\$4,500	Cost:		
FY-83 FEDCASE: CONTRACT COS 800	T: SUPPLY COST: 6,000	DATE OF COMMIT ANNUAL PROGRES	TEE APPROVAL OF S REPORT FEB	2 5 1993		
Study Objective: To produce a suitable antisera in rabbits which will be used to develop a sensitive RIA procedure for the determination of 10,25 (OH) 10 in human serum. TECHNICAL APPROACH: Preparation of a suitable conjugate of 10,25-(OH) 10, to which a large protein may be attached. Injection of this protein Hipten into rabbits for production of a suitable antisera. PROCESS DURING FY-82: A suitable conjugate to 10,25 (OH) 10, has been developed. We are now ready to add the protein and follow up with the animal injections.						
Number of Subjects Studied:		•				
FY-82: None Total	(TO DATE): None	_ Before Com	יבדוס: סד אוטסי	None		
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPATI	ing in Prodect(IF BONE SO STAT	<u>=):</u>		
None	· .					
CONCLUSIONS: The production assay procedure that wing will then be employed to in selective pathological	ll be selective for o study human physi	1α,25(OH) ₂	D,. This pr	ocedure		
Flor corrors on Ancinacia EV.	22. Nana					

DATE: 140ct82 NOX UNIT I	a.: 1337-82	STATUS	: Interim X	First			
STARTING DATE: 1 Jan 82 DATE OF COMPLETION: 1 Jan 85							
KEY NORDS: Thyroid/Immun	oglobulin						
TITLE CF PROJECT: Relations Position in the Skin	hip of Thyroid Dis	ease an	d IgG, IgM, a	ind IgA De			
PRINCIPAL INVESTIGATOR(S): K	.D. Burman, LTC, M	<u>c</u>					
ASSOCIATE INVESTIGATOR(S): 0	.G. Rodman	· 					
FACILITY: KRAYE	DEPT/Syc: Endo	crine/D	ermatology	····			
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Созт:	ACCUMULATIVE S	WARLY COST:			
FY-83 FEECASE: CONTRACT COS	T: Supply Cost:	DATE OF AMMUAL	COMMITTEE APPROPRIES REPORT	FEB 2 5 1983			
STUDY OBJECTIVE: To determine and other evidence of immediate of immediate and other evidence of immediate. Skin biology of the state o	opsies of effected	e and a	utoimmuno thy	yroid disease ea.			
Number of Subjects Studged:							
FY-82: 3 TOTAL	(TO DATE): 3	BEFO	RE COMPLETION OF	STUDY:			
SERIOUS/UNEXPECTED SIDE EFFECT	s in Subjects Participat	ing in P	ROUECT(IF NONE S	O STATE):			
None	·	·					
CONCLUSIONS: Immuno complin tissue in patients wi with effected skin to combe associated with antibo	th uneffected diseanme to enter the pro	ase. W	e are waiting	until patients			
PUBLICATIONS OR ABSTRACTS. FY-8	32:						

Study Objective Cont'd.

have immunoflourescently determined antibodies in their skin.

DATE: 250ct82	ATE: 250ct82 NORK UNIT No.: 1338-82				STATUS: INTERIM X FINAL			
STARTILIS PLATE: 1982 DATE OF COMPLETION:								
KEY NORDS: F	Receptors/Mo	nonuclear						
TITLE OF PROJECT:	Membrane	receptors in per	ipheral cir	culating mono	nuclear cells			
			•					
PRINCIPAL INVESTI	GATOR(S): Ke	nneth D. Burmar	, MD					
ASSOCIATE INVESTI	GATOR(S):	·	· · · · · · · · · · · · · · · · · · ·					
FACILITY: HRANC		DEPT/SVC:			·			
Accumulative PEDC	ASE Cost:	Accumulative Contra	icr Cost:	ACCUMULATIVE :	SUPPLY COST:			
FY-83 PEDCASE:	CONTRACT COST:	SUPPLY COST:	DATE OF FINHUAL	COMMITTEE APPRI PROGRESS REPORT	OVAL 0= 25 Feb 83			
Study Osjective:	To measure	membrane rece	ptors in hu	imans.				
		•						
TECHE CAL APPROAC	H: Isolation	of white cells						
PROGRESS DURING F exercise	Y-82: Beta≀	receptors measur	ed in 20 p	atients found	to increase wi			
Number of Subject	s Siudied:			.—.———————————————————————————————————				
FY-82: 20	TOTAL (TO DATE): 20	Вего	RE COMPLETION O	= Sтизу <u>:</u> 100			
Serious/Unexpected None	SIDE EFFECTS	IN SUBJECTS PARTICI	PATING IN P	ROJECT(IF NONE	:(STATE			
		ors increase in e		2) Beta recepto	or binding is			
blocked by circ	ulating immu	noglobulin recep	tors.					
PUBLICATIONS OR A								

DATE: 250ct82	Hask Beet No.	: 1339-82	Seatus	: INTERIM	X First	
STARTING DATE: 1982 DATE OF COMPLETION:						
Key Vioras:	Immunolog	y/Thyroid		•		
TITLE OF PROJECT:	Immunolog	y of Thyroid Dise	ase			
			•			
PRINCIPAL INVESTI	GATOR(S): Ke	nneth D. Burman,	LTC, M	c ·	* # ₂ 4	
ASSOCIATE INVESTI	GATOR(S): Jai	mes Baker, MD, Ro	bert S	mallridge,	MD	
FACILITY: KRAYE		DEPT/S/C:				******
Acamerative PEOC	ASE Cost:	ACCUMPLATIVE CONTRACT	Cost:	ACCUMULATI	VE SUPPLY COST	- Г:
FY-83 PECASE:	CONTRACT COST:	SUPPLY COST:	DATE OF	COMMITTEE A PROGRESS REP	PPROVAL OF CRT FFR 25	1043
TECHNICAL APPROAC	H: The techn	ical approach is a c	omplex	method invell as deve	volving ident loping compl	ification lex
		elop antibodies aga e developed an ELI				
formed in Grave	s' disease and	have determined t	that 23	of 25 untrea	ated Graves'	patients
have abnormal v			:		 	
FY-82 <u>: 25</u>	Total ((TO DATE): 25	Befo	RE COMPLETIO	אי סד Study <u>: 7</u>	<u>'0</u>
SERIOUS/UNEXPECTE	D SIDE EFFECTS	IN SUBJECTS PARTICIPA	rice in	מו זו)דסבנכה	NE SO STATE):	•
None		• • •	•			
Conclusions: probe when investigates.		esensitivity and spe mechanism by which				
·.	•.				•	
Stimulated Horn	sitive and Ra mone Recepto	2: pid Enzyme Linked or Antibodies. JR I n Federation for C	Baker, `	YG Lukes, R		

DATE: 250ct82	Hase Burr No	1340-8	2	STATUS	Interim	ΧF	1024.
STARTING DATE: 1982 DATE OF COMPLETION:							
KEY VONES: Be	ta Recepto	rs/Thyroid			•		
TITLE OF PROJECT:	Adrener	gic Sensiti	vity ar	nd the 1	hyroid		
			* * .	•			
PRINCIPAL INVESTI	GATOR(S):	Kenneth D	Burma	in, LTC	MC ·		
ASSOCIATE INVESTI	GATOR(S):	Keith Lat	ham	·			
FACILITY: KRAYE	· ·	DEPT/SVC	:				
ACCUMULATIVE PEDC	ASS Cost:	ACCUMPLATIVE	CONTRACT	Cost:	Accurulati	VE SUPP	PLY COST:
FY-83 PECCASE:	CONTRACT COST	T: SUPPLY Cos	iT: -	DATE OF ASSUME	COMMITTEE P	PPROVAL CRT	0F EB 2 5 1983
STUDY OBJECTIVE: receptors when to TECHNICAL APPROACE and to develop meta-receptors. Prosess During February and that he lives of Subject FY-82: 25	H: To Development of some solution of the solu	op a beta recorrening for developed have determined.	antiboo a sensinined thid people	assay who dies that tive and lat they e have t	en is sensit have been specific as are presen	formersay for tin the	nd specific ed against or measuring yroid gland of receptors.
SERIOUS/UNEXPECTE	D SIDE EFFECTS	S IN SUBJECTS I	'ARTICIPA	TING IN P	ROJECT(IF NO	Ce six	STATE):
None Conclusions:	Boto roo				in shounded	*iaaa	d
different in hype		eptor antiboo d euthyroid p		present	in thyroid	ussue	and are no
							••
PUBLICATIONS OR A			•				
Beta Receptors . Smallridge, Lath						man,	Ferguson,

DISPOSITION FORM For use of this form, see AR 340-15, the proponent opensy is TAGCEN. REFERENCE OR OFFICE SYMBOL HSHL-ME Review of Annual Progress Reports

Dr. Wayman Cheatham FROM Dr. Kenneth D. Brman DATE 27 Jan 83 CMT 1
DCI Burman/lmm/6-1743

1. This DF is in response to your questions concerning the budget of \$16,200.00 FY 83 and 84 inclusive for protocol #1340-82 entitled "Adrenergic Sensitivity and the Thyroid Gland", whereas the original request was \$3,900.00. The reason for this discrepancy mainly relates to the interesting results which have been found that indicate that immunoglobulins circulate and initiate disease and that these immunoglobulins have characteristics of beta receptors. The enhanced funding mainly relates to previous communications with the Department of Clinical Investigation concerning making a hybridoma against the white cells of patients who make these particular antibodies. This hybridoma protocol has been devised and supported by the Department of Clinical Investigation; the supplies which are necessary for the development of this approved hydridoma contract represent the main difference in the price. We expect that this protocol will continue as it is giving tremendously interesting results. However, the cost in the following years will not be as high and, in fact, we fully expect the cost in FY 84 will probably reach half of that requested.

KENNETH D. BURMAN, M.D.

LTC, MC

Assistant Chief, Kyle Metabolic Unit and Endocrine-Metabolic Service

POSTED:

2 FEB 1983

A post of the second of Colors of C

DATE: 15 NOV HORK UNIT N	0.: 1343-82	STATUS: INTERIM X	Free				
STARTING DATE: JUNE 1982 DATE OF COMPLETION:							
KEY NORDS:	ospholipid vesicle						
TITLE OF PROJECT: Purificati	on of thyrotropin	receptor from thyro	id gland and				
incorporation into unila	imeliar phospholip.						
PRINCIPAL INVESTIGATOR(s): CPT Patricia Young, PhD MSC							
ASSOCIATE INVESTIGATOR(S): L'	TC Kenneth Burman,	MD Yvonne Lukes					
FACILITY: WRANG	DEPT/Svc: Clin	ical Investigation					
ACCUMULATIVE MEDICASE COST:	ACCUHULATIVE CONTRACT	Cost: Accumulative S	UPPLY COST:				
FY-83 PEDCASE: CONTRACT, COS	T: SUPPLY COST: 5,000	DATE OF COMMITTEE APPRO FINNUAL PROGRESS REPORT	FEB 2 5 1997				
STUDY 03JECTIVE: To obtain incorporate it into a u	biologically acti nilamellar phospho	ve purified, TSH rec lipid vesicle.	eptor and				
TECHNICAL APPROACH: TSH rece	ptor purification	will proceed by attracting the receptor	inity chomatography. r with lecithin hy.				
and deoxycholate followed by dialysis and column chomatography. PROGRESS DURING FY-82: We have purified a TSH receptor from bovine thyroid and are ready to proceed with a human TSH receptor purification. We have synthesited unilamellar vesicles not containing the receptor and tested all							
inchases of the methodolo	87.						
FY-82: 0 TOTAL	(TO DATE): 0	BEFORE CONSLETION OF	STUDY: O				
Serious/Unexpected Side Effects No serious /unexpected	s in Subjects Participal side effects	ING IN PROJECT(IF NONE S	O STATE):				
CONCLUSIONS:							
NONE							
PUBLICATIONS OR ABSTRACTS, FY-8	2:						

NONE

DATE: 8 Sept 82	Hoek Unit No.	: 1342-82	STATUS	: INTERIM	Space x	
STARTING DATE: NO	ot yet begu	n DATE (E COMPLET	1011: 1985		
		tidine, Spironal				
TITLE OF PROJECT: Spironolactone	Treatment	of Hirsuitism wi	th topic	cal Cimetidi	ne or topical	
PRINCIPAL INVESTIG		obert A. Vigersk				
ASSOCIATE INVESTIG	ATOR(S): A	lbert Szkutnik,				
FACILITY: KRAYC		DEPT/SVC: Kyl	e Metabo	lic Unit		
Accumulative PEDCA 0	SE Cost:	ACCUMULATIVE CONTRACTOR	r Cost:	ACCUMULATIVE . 0	SUPPLY COST:	
	CONTRACT COST: \$5,000	SUPPLY COST:	DATE OF FINNUAL	COMITTEE REPORT PROGRESS REPORT	FEB 2 5 1983	
		rsuit women by tone or cimetidine		al applicat	ion of the	
be applied 3 timed determined before alone will PROGRESS DURING FY	mes daily tre and afte loccur bef	will be incorpo o the affected a r and at the end ore or after the rotocol has not	reas. 'of a 3	The hair grown month period in	wth rate will d. A 3 month a double bli	be trial of nd fashion
Surgeon General Number of Subjects						
			_	_		
FY-82 <u>: 0</u>	IOTAL (TO DATE): 0	BEFO	RE COMPLETION O	OF STUDY: 20	
Serious/Unexpected Not applica		IN SUBJECTS PARTICIPA	TING IN P	ROUECT(15 NONE	SO STATE):	
CONCLUSIONS: We	hope to be	gin the study be	fore the	e end of the	calendar yea	r.
•						
PUBLICATIONS OR AB	STRACTS, FY-82	: None				

Date:	HORK UNIT NO	.: 1415	STATUS	: INTERIM	X	Final
STARTING DATE: 1978 DATE OF COMPLETION: Key Moras: Esophageal Clearance, Esophageal Transit, Radioisotopic Scan, Esophageal Monometry						
KEY HORDS: ESOP	hageal Cle	arance, Esophagea	l Trans	it, Esoph	agea	1 Monometry
TITLE OF PROJECT:	Esophagea	l Acid Clearing:	Quanti	tated by	Radio	oisotopic Scan
PRINCIPAL INVESTIG	SATOR(S): CO	L Lawrence F. John	nson. M	.D.		
ASSOCIATE INVESTIG	GATOR(S): LT	C Roy K. H. Wong,	M.D.			
FACILITY: WRANC		DEPT/Svc: Gast	roenter	ology Ser	vice	,
Accumulative PEDC	ASE Cost:	ACCUMULATIVE CONTRACT 0	Cost:		ive Su 500.	upply Cost: 00
FY-83 PEDCASE:	CONTRACT COST	: Supply Cost: \$500,00	Date of Annual	Cormittee P Progress Rep	rort Port	FEB 2 5 1983
the radioisote agent, bethand TECHNICAL APPROACH in that the part of time rather PROGRESS DURING FOR to reprogramm the method of Humber of Susuects	opic techniechol, on e schol, on e sechol, on e sechol, on e sechol r than to s (-82: During ing the com data colle s Studied:	puter to analyze ction and change taken p	udy the earance made i llow a ntrolle ges (abthe datin the lace of	n the des specific d fashion love) have a in this design of	of a sign time h. bee fas the 82.	of the protocol s over a period n made in addition hion. Reprogrammin
FY-82: 0 SERIOUS/UNEXPECTED		(TO DATE): 7 IN SUBJECTS PARTICIPA				STUDY: 20
····		NONE				
at specific i	ntervals ve ol. Reprog	e design of the persus swallowing i pramming of the co	n an ac	i lib fash	nion	has been added
PUBLICATIONS OF AS	STRACTS FY-8	2: NONE				

DATE: 5 Oct 82 Mosk Eyer?	11.: 1416	GARBS.	Person X From	
STARTING BATE:	T; z c	<u>- (689.6110)</u>	:	
Kay Novas: Achalasia, Eso Time of Phoseom: Esophagea Method	phageal Emptying, 1 Emptying in Acha	Postdilat lasia: Qu	on, antitated by Radioiso	topic
PRINCIPAL INVESTIGATOR(S): CO	L Lawrence F. John	son, M.D.		
Associate Livesticator(s): LT	C Roy K. H. Wong, !	M.D.		
FACILITY: WAYE	DEPT/Syc: Gast	roenterol	ogy Service	
FACILITY: MPANC ACCUMULATIVE NEBUASE COST: 0	ACCUMULATIVE CONTRACT	Cosr: A	CCUMULATIVE SUPPLY COST:	
O FY-33 YEDUSE: CONTRACT COS O STUDY OBJECTIVE: To study t				
TECHNICAL FREEDWCH: To measu with achalasia. Technet an esophageal emptying pages 100000 FY-82: ~7 pa	ium was tagged to profile was establi	cornflake: shed. Pat	s and milk and from the	is
Museum of Subjects Studied:				
FY-32: 7 TOTAL	(TO DATE): 20	Before	CONSERTION OF STUDY: 30	
Statious/Ulewscred Side Effect	NONE			
Concussions: Data concerni 5 years and continues to				

with a radioisotopic scan pre and post dilation.

Table Oct 82 Max Ever the	: 1417	Status: Interior X 1,000	
Startes Mac: 1977	Far 1	Coverencia 1983	
Key Nords:			
Time of Project: Plasma Lig	andin in Liver Dis	sease	
Paradiam Invasication(s): MAJ	Maria H. Sjogren,	M.D.	
ASSIGNATE INVESTIGATOR(S): COL	L. F. Johnson, M.D	D., LTC R. W. Sjogren, M.D.	
FACILITY: 18788	Gastr Gastr	roenterology Service	
Accumulative (SECCAST Cost)	Focus Catting Contract C	Cuat: Act on Tive State Car.	
F7-55 PEDCASE: Contract Costs	Stanta Cost:	PAGE OF A MOTTOR OF FEB 25 1993	
Study Councillate: The aim of potentially more sensitive available tests.	the study is to as indicator of hepa	ssess plasma ligandin levels as a atocellular damage than currently	
TECHNICAL FARRONCH: Patients	having liver biops	sies at Walter Reed Army Medical An aliquot is removed and frozen	Center
plasma ligandin content.	Plasma ligandin co	ontent is determined by a (see be	low)
Property Poster FY-82: 23 samp bringing the total to 349	les were collected samples. It is ar	from 1 Oct 81 through 30 Sep 82 nticipated that when approximate	y 500
samples are available for	analysis, statisti	ically meaningful results can be	drawn.
Allement of Subjects Studied:			
FY-62: 23 Tora (TO DATE): 349	BEFORE COMMUNICATION OF STUDY: 500 (est	timated)
STR. 005/UNE PECTED SIDE EFFECTS	TH SUBJECTS FARTICIPATH None	ING IN PROJECT(15 NOWE SO STATE):	
Characteris: Not available			
FUEL ICATIONS CO ABSTRACTS. FY-82	: None		

Technical Approach, continued: sensitive and quantitative radioimmunoassay technique at Albert Einstein College of Medicine in New York. Correlations between pathological diagnosis, enzyme values and ligandin levels will be made by standard statistical methods.

DATE: 28 Sep 82 MORK BULT No.: 1419 STATUS: INTERIM X FIRM	
STARTING DATE: 23 August 1977 DATE OF COMPLETION: 5 years	
Key Nords: Cricopharyngeal Bar	
TITLE CF PROJECT: Cricopharyngeal Bar: A Video Manometric Study	
PRINCIPAL INVESTIGATOR(s): COL Lawrence F. Johnson, M.D.	
ASSOCIATE INVESTIGATOR(s): James W. Kikendall, M.D., David J. Curtis, M.D.	
FACILITY: WRANC DEPT/Svc: gastroenterology Service	
ACCUMULATIVE NEDCASE COST: ACCUMULATIVE CONTRACT COST: ACCUMULATIVE SUPPLY COST: N/A N/A	
FY-83 MEDCASE: CONTRACT COST: SUPPLY COST: BATE OF COMMITTEE APPROVAL DE 1983	l
STUDY DESCRIVE: To study the functional significance of a cricopharyngeal shown in barium swallow.	
TECHNICAL APPROACH: This is a synchronized manometric video tape fluoroscopi of swallowing disorders of the hypopharyngeal, cricopharyngeal region an esophagus.	c study d upper
PROSRESS DURING FY-82: We are awaiting installation of cable connecting the Gology Service manometric suite with the split screen capacity at WRAIR, the final link necessary prior to beginning this protocol. No subjects	which is
HUMBER OF SUBJECTS STUDIED:	10 normal
FY-82: 0 TOTAL (TO DATE): 0 BEFORE COMPLETION OF STUDY: 20	
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE): NONE	
Conclusions: Deferred pending further investigation	
PUBLICATIONS OR ABSTRACTS, FY-82: NONE	

DATE: 5 Oct 82 Mosk Unit N	o.: 1420	STATUS: INTERIM X	Fire
STARTING DATE: 1978	DATE OF	COMPLETION:	
Key Kopas: cat esophagus,	adenyl cyclase, gua	inyl cyclase, lower	esophageal sphincte
TITLE OF PROJECT: Adenyl Cyc	clase and Guanyl Cy	clase Activity in t	he Cat Esophagus
PRINCIPAL INVESTIGATOR(S): L	TC Roy K. H. Wong.	M.D.	
ASSOCIATE INVESTIGATOR(S): CI	OL Lawrence F. Johr	ison, M.D.	
FACILITY: HRAYC	DEPT/Svc: Gastr	oenterology Service	<u>!</u>
ACCUMULATIVE MEDCASE COST:	ACCUMULATIVE CONTRACT (COST: ACCUMULATIVE S	JPPLY COST:
0		\$10,000	
FY-83 FERCASE CONTRACT Cost \$50,000	T: Supery Cost: \$10,000	DATE OF COMMITTEE APPROVE	/AL 0# FEB 2.5, 799()
STUDY OBJECTIVE: To study the effects of the lower eson these pharmacologic agent TECHNICAL APPROACH: Since the have been tried including this protocol would be significant to do the enzyme assays of the control of the enzyme assays of the control of the enzyme assays of the enzyme assays of the control of the enzyme assays of the enzyme assay	phageal sphincter in the intracelle inception of this the cat, opossum, tudied utilizing the ess in FY82 has been	n cats. To study the ular enzyme ader ader protocol, several and finally the rate rabbit as an animal control of the control o	ne effects of anyl cyclase. animal models abbit. Presently, and model.
Murses of Susuects Studied:			
- · · · · · · · · · · · · · · · · · · ·	(TO DATE): 30	_ Before Completion of	Stuby:
SERIOUS/UNEXPECTED SIDE EFFECTS	IN SUBJECTS PARTICIPATI	NG IN PROJECT(IF HOME SO	STATE):
CONCLUSIONS: Continued prol do enzyme assays have har involved in locating an for these enzyme assays.	mpered the feasibil	ity of this project	. Presently I am
PUBLICATIONS OR ABSTRACTS, FY-8	2:		

[ATE: 20 Sep 82 16	RK UNIT NO.: 14	22	TATUS: INTERIM X	FINAL
STARTING DATE:		DATE OF COM	PLETION:	
KEY WORDS:				
TITLE OF PROJECT: The Se with L	quential Staging aparoscopy and L		er in Hodgkin's Dis	ease
PRINCIPAL INVESTIGATOR(S): LTC David A.	Peura, M.D	•	
ASSOCIATE INVESTIGATOR(S	3):		rence F. Johnson, n D'Avis, LTC Grant	Taylor
FACILITY: WRAMC	DEP1:/SVC	Gastroent	erology Service	
ACCUMULATIVE MEDCASE COST: None	Accumulati Cost:none	VE CONTRACT	ACCUMULA Cost:n	TIVE SUPPLY
		PPLY COST:	DATE OF COMMITTE ANNUAL PROGRESS	_
	uate the role of 's patients.	laparoscop	y in clinical stage	III or IV
TECHNICAL APPROACH: See	<u>PLAN</u> section of	original p	rotocol.	
PROGRESS DURING FY-82: since no patients have be following their laparosc protocol should be incur following his laparoscop no funding involved in t	een referred to opic examination red since an occite procedure; ar	the Clinic n. It is fe asional pat	that have undergone lt that continuatio ient will undergo l	laparotomy n of this aparotomy
HUMBER OF SUBJECTS TO BE	STUDIED BEFORE	COMPLETION	OF STUDY:	
SERIOUS/UNEXPECTED SIDE	EFFECTS IN SUBJ	ECTS PARTICI	PATING IN PROJECT:	•
CONCLUSIONS: No conclusi have been assessed into		at this ti	me since no additio	nal patients
PUBLICATIONS OR ABSTRACT	s FY-e2. None			

DATE: 5 Oct 82	HORK UNIT NO	: 1426	STATUS	: INTERIM	_X	Final	_
STARTING DATE:	1976	11	TATE OF COMPLET	104:		~	_
KEY KORDS: Indon	methacin, r	abbit esophag	us, acid in	duced str	ictu	res	_
Time of Project: Strictures on	The Effect the Rabbit (of Indometha Esophagus	cin on Expe	rimentall	y Ind	duced Acid	_
PRINCIPAL INVESTIG	GATOR(S): LT	C Roy K. H. W	ong, M.D.				_
ASSOCIATE INVESTI	GATOR(S): CO	L Lawrence F.	Johnson, M	.D.			
FACILITY: WRANC		DEPT/SVC:	Gastroenter	ology Ser	vice		_
ACCUMULATIVE PEDC \$5,000.00	ASE Cost:	Accumulative Co:	ITRACT COST:		iv≘ Su ,000.(-
FY-83 FEDCASE: \$5.000	CONTRACT COST \$5.000	: Supply Cost: \$15.000	DATE OF FANNUAL	COMMITTEE PROGRESS RE	FJPROV PORT	/AL 0= FEB 2 5 198	- <u>-</u> 3
Study OBJECTIVE:	To study the rabbits	ne effect of	indomethaci	n in prev	enti	ng acid in	duced
TECHNICAL APPROACE severe exophage swallows for the	itis. The	animals are t	hen followe	d by esop			
PROGRESS DURING F this protocol h animals have be	<u>Y-82</u> : Presen has been at	tly, with the tempted. Ani	addition o	f a new t een procu	red a	and present	inning tly 5
MUMBER OF SUBJECTS							-
FY-82 <u>: 5</u>	TOTAL	(TO DATE): 40	BEFO	RE COMPLETI	CN 0F	STUDY:	-
SER LOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PART		ROJECT(IF N	OS ENG	STATE):	- .
Conclusions: This year as more to	s study wil echnical he	l be actively lp has been a	pursued at vailable.	the begi	nnin	g of this	fiscal
PUBLICATIONS OR AE	STRACTS FY-82	<u>:</u>	·	······································			_

						
DATE: 5 Oct 82 HORK UN	ıт No.: 1427	STATUS	INTERIM	X	First	
STARTING DATE: 1977 ACHATASTA, E	DATE (F COMPLET	ICN:	ehnt	aline.	
Key loops Mitroal veeri	ne.					
Time of Project: Nitrog Treatment of Achalasi	lycerine, Terbutalin	e, and A	lminophyll	ine	in the	
PRINCIPAL INVESTIGATOR(S):						
ASSOCIATE INVESTIGATOR(S):						
FACILITY: WRANC	DEPT/Svc: Gast	roenter	ology Serv	rice		
Accumulative MEDCASE Cost:	ACCUMULATIVE CONTRACTOR	r Cost:	ACCUMULAT \$500	.00 .00	UPPLY COST:	
FY-83 FEREASE: CONTRACT	Cost: \$1284 Cost:	DATE OF FAMUAL	COMMITTEE / PROGRESS REA	PPRO	VAL OF FEB 2 5 1983	
STUDY OBJECTIVE: To stude terbutaline in patier	its with achalasia					
TECHNICAL APPROACH: Inser infuse various pharma changes in LESP under	colodic adents and d	etermin	o changes.	. Põ	itients with	Signinica
PROGRESS DURING FY-82: Se						
MUMBER OF SUBJECTS STUDIED	:	~				
FY-82 <u>: 7</u> T	OTAL (TO DATE): 13	BEFO	DRE COMPLETIO	0N OF	STUDY: 20	
SERIOUS/UNEXPECTED SIDE EF	FECTS IN SUBJECTS PARTICIPA NONE	Ating in	PROJECT(IF N	ONE S	O STATE):	
CONCLUSIONS: Study is goompletion sometime	progressing fairly rain FY 83.	pidly a	nd is exp	ecte	d to come to)
·						
	_					
PUBLICATIONS OR ABSTRACTS. Gastroenterology	FY-82: Abstracts have	been s	ubmitted	in F	Y 80,	

DATE: 6 Oct 82 Now Liver in	1429	Studies Large X 1 175	
STARTING DATE: FY80	[A, 7 c	s Commerces 5 years	
Key Noros:			
Time da Paosect: Colchici A Multi-(ne Therapy of Alcoh Center Randomized (nolic Liver Disease Controlled Study	
Padicipal Investigator(s): M	AJ Maria H. Sjogre	n M.D.	
Associate livesticator(s): Li	TC David A. Peura,	M.D., LTC Michael A. Dunn, M.D.	
FACILITY: WRANC	DEPT/Syc: Gasti	roenterology Service	
Accumulative MEDCASE Cost:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:	
FY-33 PEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COUNTITIES APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983	
alcoholic cirrhosis. TECHRICAL FARADARH: Please of Paudamon Pureus FY-82: In the School of Medicine has re	refer to original prices is multi-national candomized to date 2	ongoing protocol, Emory University 20 patients with alcoholic hepatiti	S,
the Center for Advanced S Manage of Scouncis Scotted:	Studies of the Nat	ional Polytechnical Institute,(see	below)
FY-87: Total	(TO DATE): 45	Before Crossetten of Stepv: 150 (est	imated)
Shalousy CHEMBERTED Side EFFECT	s in Subjects Exiticial	TING IN PACUEOUS IN NOME SO TOWED)	
Concusions: 45 patients a been noted. The data ha		evaluaBed. No adverse effects have ed yet.	<u> </u>
PUBLICATIONS OR ABSTRACTS, FY-	S2: None		

Progress During FY-82, continued: Mexico City has entered 19 patients and the Tale-New Haven University School of Medicine, 6 patients with alcoholic liver disease at WRAMC, 1 patient is currently being evaluated into the study.

				
DATE: 28 Sep 82 HOPK UNIT N	lo.: 1431	STATUS: INTERIN X FINAL		
STARTING DATE: December 19	80 DATE OF	<u> </u>		
Key Horas: Reflux Esopha				
TITLE OF PROJECT: A Douple in Promoting Healing an	-blind Clinical Trid d Decreasing Sympton	al of the Efficacy of Indomethams of Peptic Esophagitis.	ıcin	
PRINCIPAL INVESTIGATOR(S): MA CP ASSOCIATE INVESTIGATOR(S): LC	J Dennis R. Sinar T Donald Castell (U DR E. J. Cattau. MA	SN), MAJ J. Walter Kikendall, J Thomas P. Gage, LTC J. Rice		
FACILITY: HRANC		oenterology Service		
ACCUMULATIVE NEDCASE COST:	ACCUHULATIVE CONTRACT (COST: ACCUMULATIVE SUPPLY COST:		
FY-83 FEDCASE: CONTRACT COS	T: Supply Cost:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2.5 1983		
Study OBJECTIVE: To investi and decreasing symptoms		f Indomethacin in promoting hea	ling	
will be entered into a Indomethacin upon heali	double-blind cross on a cross of their signs a	nd symptomatic reflux esophagit over study of the effect of nd symptoms of esophagitis.		
PROGRESS DURING FY-82: No pa no patiets who met the	tients at WRAMC wer	e entered into this protocol be	cause	
MUMBER OF SUBJECTS STUDIED:				
FY-82: TOTAL	(TO DATE):	BEFORE COMPLETION OF STUDY: Study	Terminated	
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE): N/A				
patients due to the str	ict entry criteria cluding the princip	of the difficulty in finding so of the protocol and because seval investigator have moved to do not with the Military.	/eral	
PUBLICATIONS OR ABSTRACTS. FY-S	32: None			

FY 83 - Funding requirements: none are anticipated.

DATE: 5 Oct 82 HORK GNIT N	o.: 1432	STATUS: INTERIM X FINAL	_
STARTING DATE: 1980	DATE OF	F COMPLETION:	_
Key Words: Lithium, Cytop Time of Project: Lithium, PGE ₂ as Cytoprotective A	Nicotinic Acid, Am	imethyl PGE ₂ , <u>Nicotinic acid</u> , inophylline, and 16, 16, Dimet	Aminophylline hyl -
PRINCIPAL INVESTIGATOR(S): LT			_
ASSOCIATE INVESTIGATOR(S): CO	L Lawrence F. John	son, M.D.	-
FACILITY: KRAYC	DEPT/Svc: Gast	roenterology Service	_
ACCUMURATIVE PEDCASE COST: \$10,000.00	ACCUMULATIVE CONTRACT 0	\$20,000.00	- _
FY-83 PEDCASE: Contract Cos \$5,000 \$10,000	T: SUPPLY COST: \$15,000	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 198	<u>1</u> 3
aminophylline, PGE ₂ on g	astric cytoprotect		
ETOH is instilled into t	heir stomachs. Th	the pharmacologic agent, then e animals are then sacrificed	and
graded for degree of hem PROSRESS DURING FY-82: The s protective data is in pr for publication are unde	econd revision of ogress. Presently	manuscript on some of the cyto, additional work to fulfill r	r- equirements
MUMBER OF SUBJECTS STUDIED:			-
FY-82:~1,00 animals Total (rats)	(TO DATE):	BEFORE COMPLETION OF STUDY:	_
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPA	TING IN PROJECT(IF NONE SO STATE):	- .
CONCLUSIONS: Progress in t further work concerning o	his particular pro ytoprotection is p	tocol has been substantial, an resently being investigated.	ā
Publications or Abstracts, FY-Work being reviewed	82: Abstract submit	tted FY81 in a major gastroenterology jou	- urnal

DATE: 5 Oct 82 HORK ENIT N	o.: 1433	STATUS: INTERIM X	Final
STARTING DATE:	Date of	COMPLETION:	Acid Infusion
Key Kords: Gastroesophage Title of Project: Developme	al Reflux, Esophag nt of an Animal Mod	itis, Radioisotopic del for Gastroesopha	Labeling, Organ Culture
PRINCIPAL INVESTIGATOR(S): LT			
ASSOCIATE INVESTIGATOR(S): CC	L Lawrence F. Johns	son, M.D.	
FACILITY: HRAYC	DEPT/SVC: Gast	coenterology Service	
ACCUMULATIVE MEDICASE COST: \$15,000.00	ACCUMULATIVE CONTRACT		
FY-83 i EDCASE: CONTRACT COS \$10,000 \$5,000	T: SUPPLY COST: \$10.000	DATE OF COMMITTEE APPROVE FANDAL PROGRESS REPORT	AL OF FEB 2 5 1983
STUDY OBJECTIVE: To develop into the esophagus of a as measured quantitative TECHNICAL APPROACH: Rabbits agus while U.IN HCl is i animals are sacrificed degree of change. PROSRESS BURING FY-82: ~ 40 groups of animals with cuptake and measuring the	rabbit. Studies in the ly & qualitatively are anesthetized, a nfused for 30 mins gross and histologanimals have been stated to the latest the l	nvolving histology, (radioautography)ar a catheter is then p a after varying peri gic sections made an atudied in FY 82 uti	thymidine uptake e underway. laced in the esoph- ods of infusion, the d grade for the lizing various
MUMBER OF SUBJECTS STUDIED:			
FY-82: 40 TOTAL	(TO DATE): 40	_ BEFORE COMPLETION OF	STUDY: 80
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPATION NONE	ING IN PROJECT(IF HOME SO	STATE):
CONCLUSIONS: Significant procedures in the laborations or Abstracts, FY-6	One gastroenterolo tions of acid in the radioactive DNA ography. In additing the addi	gy fellow has studie e rabbit esophagus a and also to initiate on, we are at preser	ed 40 animals and has utilized e the assembly nt setting up these

Progress During FY-82 continued: studying samples for radioautography.

DATE: 5 Oct 82 HORK GALT M	o.: 1435	STATUS: INTERIM X FIRM		
STARTING DATE: FY81	DATE O	F COMPLETION:		
KEY MORDS: Achalasia, Gene	tic linkage, HLA t	cyping		
TITLE OF PROJECT: Genetic L	inkage in Achalasi	a		
		•		
PRINCIPAL INVESTIGATOR(S): LT	C Roy K. H. Wong,	M.D.		
ASSOCIATE INVESTIGATOR(S): CO	L Lawrence L Johns	on, M.D.		
FACILITY: HRAYC	DEPT/SVC: Gast	roenterology Service		
ACCUMULATIVE TEDCASE COST:	ACCUMULATIVE CONTRACT			
FY-83 NEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983		
STUDY OBJECTIVE: To study t	he association of	HLA in patients with achalasia.		
TECHNICAL APPROACH: HLA Typ	ing			
PROGRESS DURING FY-82: Seven lab.	patients were typ	ped in the transplant HLA typing		
MUMBER OF SUBJECTS STUDIED:				
FY-82: 7 TOTAL (TO DATE): 22 BEFORE COMPLETION OF STUDY: 30				
SERIOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPA	TING IN PROJECT(IF NONE SO STATE):		
	NONE			
		ver the last two years, and have with HLA determinations being made.		
PUBLICATIONS OR ABSTRACTS. FY-8	32: NONE			

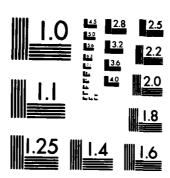
Lat: 6 Oct 82 Low Par A		Grand: Terrana X Food.	
Stanting Outer June 1981	Pare	Communication Indefinite	
87 B.			
Time of Phaneon: Magnetic Gastrointestinal Hemorrh	Field Hemostasis, age	A Proposed Treatment for Upp	er
Payrotage Treaspoortok(s): MA	J Mark T. Birns, N	1.D.	
Associate Investigatos(s): CO			
FACILITY: NOAYS	i		
Largest Same PARCASE Court	Account at the Contract	COST: ACCUMBATIVE SHEET COST.	on order)
FY-33 PEBCASE: Contract Cos 0 \$1,500	T: SUPPLY COST: \$3,000	\$3,000.00 (still Date of Committee Approval Californial Process Report FEB 25.1	983
Story Constitus: To determine Tesion in a magnetic fie	ne whether a ferro ld will stop upper	omagnetic paste applied to a r gastrointestinal bleeding e	bleeding ffectively.
at the time of initial d	iagnostic panendo:	magnetic paste via a catheter scopy for upper GI bleeding.	Passed An external
electromagnet will provi had three phase power an chemicals all on order;	ing electromagnet d water supply/dr	arrival at present; MICU #49 ain work order finished. Sup	GT, Bed I oplies and
Markey of Stautore Studies:			
FY- 2: 0 Torn	(10 DATE): 0	BEFORE COMPLETION OF STUDY: 75	5
Santous, Unexpected Side Effect	s in Subutots Parthore. N/A	NTHIS IN PROJECT(IN HONE OD STATE):	
Concussions: N/A			
Bun search of Pernagra EV-	82. N/A		

DATE: 17 Sep 82 Hork UNIT No	.: 1437	STATUS: INTERIM X	FINAL
STARTING DATE: 25 Feb 81	DATE OF	F COMPLETION:	
Key Vords:			
Title of Project: Lactose Int	tolerance and the	Diarrhea of Chemoth	erapy
PRINCIPAL INVESTIGATOR(S): Thor	mas P. Gage, LTC,	MC	
ASSOCIATE INVESTIGATOR(S): Wil	liam Major, CAPT,	MC; David A. Peura,	LTC, MC
FACILITY: MRANC	DEPT/Svc: Gastr	roenterology	
ACCUMULATIVE MEDICASE COST: NA	ACCUMULATIVE CONTRACT	Cost: Accumulative S	UPPLY COST:
FY-83 PEDCASE: CONTRACT COST	: SUPPLY COST:	DATE OF COMMITTEE APPRO ANNUAL PROGRESS REPORT	VAL OF FEB 2.5 1983
STUDY USJECTIVE: To study t	he cause of diarrh	nea in patients on c	hemotherapy
TECHNICAL APPROACH: Modifica allow for three, rather	tion as per adden than one, post-ch	dum (approv. 29 Jum emotherapy breath to	ne 1982) to ests.
PROGRESS DURING FY-82: The GI lems with the gas chroma we have been routinely e	tograph used in p	erforming the breatl	n tests; since
Mumber of Subjects Studied:			
FY-82: 0 TOTAL	(TO DATE): 0	BEFORE COMPLETION OF	Sтиру <u>:</u> 15
SERIOUS/UNEXPECTED SIDE EFFECTS	IN SUBJECTS PARTICIPAT	TING IN PROJECT(IF NONE S	: (STATE
CONCLUSIONS:		······································	
PUBLICATIONS OR ABSTRACTS. FY-8	2:		

DATE: 28 Sep 82 Mark UNIT N	o.: 1438	STATUS: INTERIM X FIMAL	
STARTING DATE: 1982	DATE O	CF COMPLETION: Indefinite, probably 198	1
Key Rosas: Gastroesophages Time of Project: Overnight Sleep Related Events Asso Factor for Pulmonary Asp	pH Monitoring of ociated with Acid	the Esophagus and Pharynx to Define Esophagopharyngeal Reflux, A Risk	
PRINCIPAL INVESTIGATOR(S) James	es W. Kikendall. M	I.D., & Lawrence F, Johnson, M.D.	
ASSOCIATE INVESTIGATOR(S):K. F	Rajagopal,M.D.,MAJ	., W. Orr,M.D., B. Jabbori,M.D.,LTC	
FACILITY: HRANC	DEPT/SVC: Gast	roenterology Service	
ACCUMAR_ATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:	
FY-83 PECASE: CONTRACT COST	T: Supply Cost: \$1,620.00	DATE OF COMMITTEE APPROVAL OF 2 5 1983	
STUDY OSJECTIVE: To define spharyngeal reflux, a risk		its associated with acid esophago- mary aspiration.	
of aspiration or with pul	lmonary illness the	nageal reflux and symptoms suggestive nought to be associated with reflux, someometric will be studied during someometric will be studied as the studied will be studied will be studied as the studied will be studied as the studied will be studied will be studied will be studied as the studied will be studi	such sleep.
PROGRESS DURING FY-82: One si was studied during the F	ubject meeting the iscal Year 1982.		
MUMBER OF SUBJECTS STUDIED:	- counc apparent t	mas dompader support (see sezow)	
FY-82: 1 TOTAL	(TO DATE): 1	BEFORE COMPLETION OF STUDY: 30	
SEPTOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPAL NONE	TING IN PROJECT(IF NONE SO STATE):	
Conclusions: Deferred pend	ing further invest	igation.	
overnight with esoph	ageal and phary cord swallowing	se subjects will be monitored rogeal pH probes, EEG, and and respiratory frequency,	
PUBLICATIONS OR ABSTRACTS, FY-8	2: None		
interpretation of the	e study. We ar determine the	rould be necessary for adequate se currently engaged in approac most efficatious means for	h –

PATE: 20 Sep 82	WORK UNIT No.: #1	.439	STATUS: INTERIM_X FINAL
STARTING DATE: 1 Jan	82	DATE OF CON	MPLETION:Estimate: 1 Jun 83
HEY MORDS: Chronic Dy	spepsia Reflux Bi	ofeedback	
Title of Project: Chr manometric mechanism	onic dyspepsia and is associated with r	excessive d reflux and t	aytime gastroesophageal reflux: herapy with biofeedback
PRINCIPAL INVESTIGATE	CR(S): Steven S Sha	y LTC	
ASSOCIATE INVESTIGATO	OR(S): Lawrence F.	Johnson COL	
FACILITY: WRAYC	Dept/Syc	Gastroen	terology
Accumulative PEDCASE Cost:	ACCUMULATI COST:	VE CONTRACT	ACCUMULATIVE SUPPLY COST: \$300.00
FY-82: MEDCASE: CO		IPPLY COST: 8150.00	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORFEB 25 198
TECHNICAL APPROACH:	n and dyspepsia Step 1: Documentat	tion reflux	by standard tests; Step 2: defining s maneuver; Step 3: biofeedback
against abdominal wa 24 hour pH monitorin	all, + Tension; Step	4: Confir	m efficacy or failure with repeate
PROGRESS DURING FY-8	2: 3 patients accru reviously studied ar	ued in addit nd treated a	tion to 4 other patients
Number of Subjects to	O BE STIDIED BEFORE	COMPLETION	OF STUDY: 10
SERIOUS/L'MEXPECTED S	IDE EFFECTS IN SUBJ	JECTS PARTIC	IPATING IN PROJECT: None
CONCLUSIONS: Prelimit of same by 24 hour p		en patients	have improved with documentation
PUBLICATIONS OR ABST	RACTS, FY-82: None	 	

AD-A129 242	ANNUAL PRO ARMY MEDIC	GRESS REPO CAL CENTER	RT FY-82 WASHINGT	ON DC T			3/4	
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MICROCOPY RESOLUTION TEST CHART NATIONAL BUREAU OF STANDARDS-1963-A

DATE: 1/17/83 NOW UNIT NO	.: 1440	STATUS	: Interim X	Final	
STARTING DATE: Oct 81	. DATE OF	COMPLET			
Key liords:			•		
TITLE CF PROJECT: Does the S Treatment	Size of an Esophage and Clinical Cours	eal Str	ricture Deter	mine Medical	
PRINCIPAL INVESTIGATOR(S): Da	vid A. Peura, LTC	MC			
	ephen R. Freeman.		MC; L. F. Joh	nson, COL, M	С
FACILITY: WRANC	DEPT/SVC: GI		,		
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE S	UPPLY COST:	
See Original Protocol	None		None		
FY-83 IEDCASE: CONTRACT COST	: Supply Cost: None	DATE OF ANNUAL	COMITTEE APPRO PROGRESS REPORT	FEB 2 5 1983	
See original protocol					
chosen? 3. Is strictur	icture size dictat	te type	e & size of d	ilator initia	allv
PROGRESS DURING FY-82: Twelve the first year of its be peptic stricture, four m	ing in place. Of				
FY-82: 12 TOTAL	(TO DATE): 12	_ Befor	RE COMPLETION OF	STUDY:	
SERIOUS/UNEXPECTED SIDE EFFECTS None	IN SUBJECTS PARTICIPATI	ing in Pi	ROUECT(IF NONE S	O STATE):	
CONCLUSIONS: No conclusions size enrolled in the stuthe goal, continuation o	dy. Because of th	e smal	1 number which	ch is far sho	rtof
PUBLICATIONS OR ABSTRACTS, FY-82	: None				

DATE: 28 Sep 82 Now Unit I	o.: 1441	STATUS: INTERIM X	First
STARTING DATE: August 1982	DATE OF	COMPLETION: 1983	
Key Nopos: Irritable bow	el syndrome, Fibromy	yalgia	
TITLE OF PROJECT: Study of Irritable Bowel Syndrome	the Prevalence of F	ibromyalgia in Patio	ents with
PRINCIPAL INVESTIGATOR(S): R	ichard J Raskin, MA	J. MC. James W. Kine	endall, MAJ, MC
ASSOCIATE INVESTIGATOR(S): L	awrence F. Johnson,	COL, MC, Richard C	. Welton, MAJ, MC
FACILITY: HRAYE	Depr/Syc: Gastro	enterology/Rheumato	logy
Accumurative MEDCASE Cost:	ACCUMULATIVE CONTRACT (1	DPPLY Cost: O (incl FY83 budget)
FY-83 PECCASE: CONTRACT COS	T: SUPPLY COST: \$1,604.40	DATE OF COMMITTEE APPROPRIATE PROGRESS REPORT	
Study Objective: To determi patients with irritable	ne the prevalence o bowel syndrome	f symptoms of fibror	nyalgia in
TECHNICAL APPROACH: Patients be identified among pati will be referred to the	ents attending the	Gastroenterology Se	rvice. These subjects
PROGRESS DURING FY-82: This the Clinical Investigati been entered into the st	protocol was only re on Committee. To d	ecently approved by ate, only one patie	fibromyalgia.
Mayber of Subjects Studied:	449.		50.0
FY-82: 1 TOTAL	(TO DATE): 1	BEFORE COMPLETION OF	50 Patients & STUDY: 50 Controls
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPATI	ng in Project(if none so	STATE):
	None	· · · · · · · · · · · · · · · · · · ·	
Conccustons: Deferred			
PUBLICATIONS OR ABSTRACTS, FY-	⁸² : None	· · · · · · · · · · · · · · · · · · ·	

Progress During FY-82: It is our plan to assign to Staff Sergeant Carol MacDonald the task of identifying the irritable bowel subjects and control subjects using a flow diagram and referring the subjects to Dr. Raskin in the Rheumatology Clinic. This should markedly speed the process of identifying these patients.

DATE: 20 Sep 82	WORK UNIT NO.: 14	1442 STATUS: INTERIM X FINAL				
STARTING DATE: 1 Jun 82 DATE OF COMPLETION: Est. 1 Jun 83						
KEY MORDS: Domperidone	e, Severe gastroeso	phageal ref	Tlux			
TITLE OF PROJECT: The Patients with Severe		one on Gast	roesophageal Reflux in Symptomatic			
PRINCIPAL INVESTIGATO	R(S): Steven S. Sh	ay LTC				
ASSOCIATE INVESTIGATO	R(S): Lawrence F.	Johnson COL	_			
FACILITY: WRAMC	DEPT/Svc	: Gastroent	erology			
ACCUMULATIVE MEDICASE COST:	Accumulati Cost:	VE CONTRACT	ACCUMULATIVE SUPPLY Cost: \$100.00			
FY-82: NEDCASE: Co	NTRACT COST: SU	PPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS PEPORTFEB 25 198:			
TECHNICAL APPROACH: S	vith domperidone Step 1: Clinically	indicate	tests for reflux show severe for 24 hours during pH monitoring			
Progress during FY-82	First 6 patients	accrued ar	nd studies completed			
NUMBER OF SUBJECTS TO	BE STUDIED BEFORE	COMPLETION	OF STUDY: 15			
SERICUS/UNEXPECTED SI	DE EFFECTS IN SUBJ	ECTS PARTIC	CIPATING IN PROJECT:			
CCNCLUSIONS: None to	date					
PUBLICATIONS OR ABSTR	ACTS, FY-82: None					

DATE .28 Sep 82 1	ow Pair (b).: 1443	Staru	s: Interio X	Fire
Starting Date:	1982	Para de Comera	TION: Indefinite	probably 1984
Kay Norda: Contico Timus de Paquadr: Ef	steroids, pancreat ficacy of Corticos	itis teroids in Sev	ere Acute Panc	reatitis in Man
Principal Investigat Associate Investigat	oa(s): James W. Kike W.M. Steinber oa(s): J. Richter.M.	ndall,MAJ, MC g,M.D., L.F. Jo D., M. Gold, M	ohnson,M.D., 1 .D., C. Rudzki	. Lipman,M.D.
FACILITY: WRANG	DEPT/S	vc: Gastroenter	ology Service	
ACCUMPLATIVE NEBCASE 0	Cost: Accumulativ	e Commact Cost: O	ASCUMULATIVE SU	HPLY COST:
FY-63 MIRCASE: Co	NTRAUT COST: SUAMLY C	OST: BATE OF	F Cornelities Approx Promassa Report	ML 08 EEG 25 193 3
Tich ica. Areanan:Phydrocortisone o	determine whether e treatment of sev atients with sever r to placebo at en ocortisone treatme	ere acute pance e acute pancre try into the s	reatitis atitis will be tudy. The cli	e randomized to inical course of
pending approval	No patients have of this protocol multicenter study.	at the various	institutions	which will be
FY-82: n	Toral (to date):	n Beec	ממר לכנוא הביסוי בה	Same 10 of UDAMC
				Srepy: ~10 at WRAMC
STRICUS/ CHEXPECTED (S)	DE EFFECTS IN SUBJECTS		houses(if have so	STATE):
Concessions: Defer	red	NONE		
Publications Cr Asste	ACTS, FY-82: NONE			
Technical Appr	oach continued	to that of	f patients o	n placebo
Progress Durin	g FY-82 continu	will be he work out f	eld in Octob	institutions er 1982 to for the conduct

DATE: 17 Sep 82 Hoss Chirt B	to.: 1444	STATUS: INTERIM X	Final.				
STARTIMS DATE: 29 Dec 81 DATE OF COMPLETION: Jan 83							
Key Koras: Intestinal Bio	psy						
Title of Project: Small Into Comparison with Standar		ng Swallowed String	as a Guide:				
PRINCIPAL INVESTIGATOR(S): The	omas P. Gage, LTC,	MC					
ASSOCIATE INVESTIGATOR(S): D	avid A. Peura, LTC	, MC; Lawrence F. Jo	hnson, COL, MC				
FACILITY: KRAYE	DEPT/Svc: Medic	ine/Gastroenterology	/				
Accumulative PEBCASE Cost:	ACCUMULATIVE CONTRACT	Cost: Accumulative S	DUPPLY COST:				
FY-83 PECCASE: CONTRACT Cos	T: SUPPLY COST:	DATE OF COMMITTEE APPROACH PROGRESS REPORT	DVAL 0F 9 1033				
STUDY DIJECTIVE: To attempt obtain intestinal biops TECHNICAL APPROACH: The patistaltic activity advances is advanced over the striperocrass During FY-82: One page 15 and 16 an	ies, and compare to ient swallows a we to the jejunum; ing. allowing rapid	the new method with s ighted string which a modified Rubin tub d advancement to the	standard techique intestinal peri- e biopsy capsule biopsy site.				
receive the standard biog	osy technique.	a so the study and t	andom zed to				
Muraer of Subjects Studied:							
FY-82: 1 TOTAL	(TO DATE): 1	BEFORE COMPLETION OF	: Sדעסעץ <u>: 15</u>				
Sarious/Unexpected Side Effects None	S IN SUBJECTS PARTICIPA	TING IN PROJECT(IF NONE S	:(STATE				
Conceusions: It is hoped the above completion date, stechnique, an extension	such that if early	results show benefi	t to the new				
Pusi ICATIONS OF ASSTRACTS, FY-8	<u>72:</u>		-				

DATE: 19 Jan 83	Hope Unit the	o.: 1445	STATUS	: leteria	X First
STARTING DATE: Ju	ne 1982	DATE	OF COMPLET	ici: End l	.983
Key Nords:					
TITLE OF PROJECT: with GER	99mTc - T	agged Chicken Li	ver Gasti	ric Emptyin	ig in Patients
		even S. Shay, LT			
ASSOCIATE INVESTIGA	ATOR(s): La	wrence F. Johnson	, COL, I	MC	
FACILITY: MRAYE	X	DEPT/SVC: GI		,	
Accurative l'EDCAS	Œ Cost:	ACCUMULATIVE CONTRAC	т Созт:	ACCUMULATIN	VE SUPPLY COST:
• • •	ONTRACT COST \$300.00	r: Supply Cost:	DATE OF	COMMITTES REPO	PROVAL OF DRT FEB 2 5 1983
STUDY CONSCIONE: C	Contributi	on of abnormal g	astric e	mptying to	GER.
TECHNICAL APPROACH: gastric emptyir	_	classified into	differe	nt GER grou	ups. Then
PROGRESS DURING FY-	-82: Studie	d 20 subjects in	luding	6 controls	
Number of Subjects	Sדעם:		~		
FY-82: 20	TOTAL	(TO DATE):	Befo	RE COMPLETION	י סוּ אַנטזע:
SERTOUS/UNEXPECTED	Side Effects	IN SUBJECTS PARTICIP	ATING IN P	אכון אן) דסבעכה	E SO STATE):
None					
CONCLUSIONS:					
Incomplete					
PUBLICATIONS OR ABS	TRACTS, FY-8	2:			

DATE: 2/16/83	HORK UNIT NO	o.:	1446		STATUS:	INTERIM	XX	Final
STARTING DATE: De	ec 82		D:	ITE OF	COMPLETIO	on: 19	84	
KEY HORDS: D1	ltazem	Acha	lasia					
Title of Project: IN PATIENT:	EFFECT	OF DI	LTAZEM	IMP	ROVING	ESOPHA	AGEAL	. EMPTYING
PRINCIPAL INVESTI	GATOR(S):	Roy	Wong.	1D				
ASSCRIATE INVESTE	GATOR(S):	L.F.	Johnso	on,	MD			
FACILITY: WRANC		D	EPT/SVC:	GI	Clinic			
Accumulative MEDC	ASE Cost:		NONE	TRACT	Cost:	ACCUMULAT	IVE SUF	PPLY COST:
FY-83 PEDCASE:	CONTRACT COS	r: Sua	PLY COST:		DATE OF (9 0 5 1983
STUDY OBJECTIVE:	Study the				ltazem	on im	provi	ing
TECHNICAL APPROACE manometric emptying st	evaluatio	give on of	n post sphing	ope	rative pressu	, foll re and	owed esop	by chageal
PROGRESS DURING F	/_82.	pati	lent pla	aced	into	protoc	01.	
HUMBER OF SUBJECTS	s Studied:							
FY-82 <u>: 1</u>	TOTAL	(TO DAT	ε) <u>:</u>	1	Before	E COMPLETI	on of S	אַנטזע <u>: 9</u>
SERIOUS/UNEXPECTED	SIDE EFFECTS	EUS NI	JECTS PARTI	CIPAT	ing in Pac	OUECT(IF I	ONE SO	STATE):
NONE			<i>'</i> .					
CONCLUSIONS:								
Ņone	, await f	urthe	er stud:	ies.				
PUBLICATIONS OR AL	STRACTS, FY-8	32:						
None								

DATE: 2/16/83 HORK UNIT NO.: 1448 STATUS: INTERIM XX FINAL
STARTING DATE: 24 August 1982 DATE OF COMPLETION: August 1983
Key Nords: Rats, Salicylic Acid, Gastric Mucosa
Time of Project: Effects of Semi-Chronic Ingestion of Lithium and ACETYLSALICYCLIC ACID ON RAT GASTRIC MUCOSA AND KIDNEY.
PRINCIPAL INVESTIGATOR(S): Roy Wong, MD
ASSOCIATE INVESTIGATOR(S): L.F. Johnson, MD
FACILITY: MRAYC DEPT/Svc: GI Clinic
ACCUMULATIVE NEDCASE COST: ACCUMULATIVE CONTRACT COST: ACCUMULATIVE SUPPLY COST: \$7,125
FY-83 I'EDCASE: CONTRACT COST: SUPPLY COST: ST, 125 Date of Committee Approval Of Annual Progress Report FEB 25 1983
Study Objective: Study GI blood loss via GI tract after injury with ASA and protection with lithium chloride.
TECHNICAL APPROACH: Lithium chloride given sub cutaneously, ASA given post operative; labelled RBC's given IV measuring of fecal blood loss measured in stool.
PROGRESS DURING FY-82: Approximately 40 animals studied with many improvement in methodology, injecting rat tails with ASA.
Murser of Subjects Studied:
FY-82: 40 TOTAL (TO DATE): 40 BEFORE COMPLETION OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE):
Conclusions:
None thus far.
PUBLICATIONS OR ABSTRACTS, FY-82:

None

2371110-2-82	1520	The first \mathbf{X}_{ij} is the second of the
Constant Parts 4-14-74	for a larger	11-12-76
Vey Mores: Cranial Radiat	ion	
TITLE OF PROJECT: CALGE # 7	411 - Combination In Chil	dhood Acute
Lymphocytic Leukemia.		
PRINCIPAL INVESTIGATOR(L): R	aymond B. Weiss, M.D.	
Associate Investigation(3):		
FACILITY: JRAYC	DEPT/Suc: Hematalogy/	Oncology - Dept. Of Med.
Accumulative MEDCASE Cost:	Accumulativa Contract Cost:	Oncology - Dept. Of Med. Accumentive Opency Const. O
FY-83 PELCASE: Coursect Cos	T: Spay Corr. Ears of Ears of	0 - - Ст мотеля Ломеромы Са Городого керс от FEB 2.5 1983
Stooy Councilys Assess role vigorous induction for h	of early cranial radiating igh risk patients. Compa	ion . Determine role of more re three reinforced maintance.
Prednisone, Methotrexate	,introthecally and L-As	omized to Reg. l. Vincristine, paraginase. Reg 2: Same plus mized to regimen II , regimen III
in the same of the same ident	ical to Reg. II but inclu	ides Dauremycin.[
Protocol has been close complete remission . 2 a		1976. 4 patients remain in
Profes of Granders Strates:		*
19-20 0 Total	(rp perr), 6 Kus	out Commentation of State Closed
terrousy dievasorial Side Easter NONE	а на Suвивота Рамијон алиша на	Propriet (if None so grant)
(1.17) P. 1915: See. 78-79 A	nnual Report.	The second secon
THE TEATTERS OF THE PACES IN	62:	

NONE

CA Stage III Hodgki	LC3# 7451 ns Disease	e (Phase III)	emothera	py and Radiotherapy of	
Cospa, jeason			M.D.		
<u>Augustes Investiga</u> Facility: 1242	, 7(3).	Paper/Syc: Hem	atology/	Oncology -Dept.Of Med.	
Accembrative (EBCAS	E Coar:	ACCUMBIATIVE CONTRAC	т Созт:	Accemblations Surply Conti	
	CHIRALT COST	: Survey Cost:	DATE CT	Co Witter Appropriate 05 1983	
followed by sing	le agent	maintance therap	v produc	on induction Chemotherapy es different frequencies	
TECHUICAL PARROWH:	Vincrist /M2 po/day	ine 1.4mg/m2 weed 1-14 - RT. Tota I a C.R. MC no longer ent	k IV X 2 1 nodal ers pati	es different frequencies rom treatment with a total- 2 - Procarbazine 100mg/m2 d irradiation ten our of 15 ents on this study. from 4/28 to 10-22-80	ay 1-14 DC
Treduicat Approvati	Vincrist /M2 po/day 22: 1. WRA 2. CAL	ine 1.4mg/m2 weed 1-14 - RT. Tota I a C.R. MC no longer ent	k IV X 2 1 nodal ers pati	2 - Procarbazine 100mg/m2 dirradiation ten our of 15	ay 1-14 DC
Prednisone C Mg. Prednisone FY-	Vincrist /M2 po/day 22: 1. WRA 2. CAL	ine 1.4mg/m2 weed 1-14 - RT. Tota I a C.R. MC no longer ent GR entered 14 pa	k IV X 2 il nodal ers pati tients f	2 - Procarbazine 100mg/m2 dirradiation ten our of 15	ay 1-14 DC
Prednisone C Mg. Predni	Vincrist /M2 po/day 22: 1. WRA 2. CAL STUDIE: TOTAL (tine 1.4mg/m2 week 1-14 - RT. Tota I a C.R. MC no longer ent GB entered 14 pa (ro DAVE): 14	k IV X 2 al nodal ers pati tients f	ents on this study.	ay 1-14 DC

Study Objective, continued: nodal irradiation, total nodal RT followed by Chemo and Chemo followed by nodal RT.

DATE: 10/2/81 MORK UNIT N	o.: 1534	STATUS: INTERIS X FIRM
STARTING DATE: 5/7/75	DATE OF	COPLETION: 10/77
KEY VORDS: MER Immunoth	erapy Myelocytic Le	ukemia.
therapy with MER as adju	vant to induction ar	Study of the Value of Immuno- nd two maintance chemotherapy
programs in Acute Myeloc	ytic Leukemia.	
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss, M	.D.
ASSOCIATE INVESTIGATOR(S):		
FACILITY: NRAMC	DEPT/Svc: Hemato	logy/ Onc. Dept. Of Med.
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT C	OST: ACCUMULATIVE SUPPLY COST:
FY-83 PEDCASE: CONTRACT COS		DATE OF COMMITTEE APPROVAL OF 2 5 1983
TECHNICAL APPROACH: Standardinfusion for 10 Days + Dance arms, 2 Including Mo	A-C and fig with Vid induction with ARA aunomycin45mg/m2/da, er l of these with o	unotherapy increases remission ance with ARA.C and 6tg with incristine Peranethasone and ARA-C A - C 100mg/m2/Day by continuous /Iv push on day 1-2-3 three maint cycling VCR and Derameithasone.
in complete remission.	patients at risk i	for relapse in 1981-82 continue
Munsex of Subjects Studied:		
FY-82: 0 TOTAL	(TO DATE): 35	BEFORE COMPLETION OF STUDY: Closed
SERIOUS/UNEXPECTED SIDE EFFECT: patient with bone marrow Ceymelinating disease.	s in Subjects Participation transplant (off si	ng in Project(if None so State): tudy) has radiation induced
CONCLUSIONS: Immuno therapy	of no-benefit with	Acute Leukemia maintancetherapy. e risk for repaspe . Study closed
PUBLICATIONS OR ABSTRACTS, FY-8	2: Cuttner S	t al : Chemimmunotherapy of
Acute Myelocytic Leukemi	_	

10-2-82	18.8 Car lb. 1535	(1 rus)	ly reading X () is a set	
Simplify Pare: 1	975	13.1 Carestina	1980	trans a state of
	yant Chemotherapy, In			=
THE CONTRACTOR	CALGB # 7581 - Long 1 ut Adjuvant Immunothe	Term Surgical Adj	uvant Systemic Ch	nemotherapy
	ac Adjavane Immunotive		odi Cimond.	
Programa de ara	Raymond B.	. Weiss, M.D.		
Annuere la care	SATON(1):			
Santa 1891	Francisco de Francis ASS Contra de Todo (1911)	- Hematalogy/On	cology - Dept.Of	Med.
discus na ne ideli	E Committee Control			
	0	0	. 0,	er resp
	0 0		FEB 2	5 1983
un un nus suuden us en. Suurkassa kassa	To compare combinati	on chemotherapy s	with or without i	immunotheran
in treatment	of stage II Breast (Cancer .	value of wathout a	immano che l'ap
	CMF VS CMFVP VS CM	IFVP with MER		5-m-1-m-1-m-
	Of the 42 patients	entered on this	study. 6 have be	en lost to
TOTAL UP ,	have died, 29 are ali no evidence of disea	ve and being to	llowed. Ut these	29 25
್ ಎಂದ ಚಿತ್ರಿಯ ಬೇಕು	\$.02165:			_
P 72 -4 0	TOTAL (10 part);	42 Page C	े अस्ति अध्यक्ति । इ.स.च्या अध्यक्ति	CALGB -800 WRAMC - 80
NONE	Some Cerecity of Structure (And the second in Free	JAMES 101-51 G1475	:
	and the same of th			
SE	ELAST YEAR			
Familian 1 78	Towns, Probability	en a marine de la companya de la co	ي از پېښې په دغه ښې د د د د د د د د د د د د د د د د د د	

SEE LAST YEAR

ASSOCIATE INVEST		ymond B. Weiss,	MaDa			
FACILITY: WRANC		DEPT/Svc: Hem	atology/	Oncology- D	ept. Of Med.	
Accumulative PED	CASE Cost:	ACCUMULATIVE CONTRAC	er Cost:	ACCUMULATIVE	SUPPLY COST:	
00		00	l n	00		
FY-83 PECASE: 00			PATE OF	Committee Rear Progress Report	OVAL UF EEB 2.5 1983	}
100mg/m2/po/	0ay 1-14.	Prednisome 4 kmg/r	12 begar	-14 , Radiot	herapy 2500	rads.
Oneganna Puntus	FY-82: [in 4] yer inters [0/22/80 Pr	Prednisome 4 lmg/r weeks to gross coatients on this for to its closur	isease.			
PROGRESS DURING WRAMC no long 4/28/80 to 1	FY-82: [in 4 ger inters 0/22/80 .Pr lred. Ts STUDIED:	weeks to gross	isease. study. re we ent	CALGB entere ered 7 pt.s	d 22 patient , 5/7 are in	s from

DATE: 10/2/82	Mosk Unit No.:	1538	STATUS	: INTERIM X FIRE	
	7/28/75	DATE OF	COMPLET	10%:	
	kin's Disease				
TITLE OF PROJECT:	CALGB: ₩ 7552		Chemoth kin's I	nerapy and Immunotherapy Disease.	for
PRINCIPAL INVESTI	GATGR(s): Ray	ymond B. Weiss,	M.D.		
ASSOCIATE INVESTI	GATOR(S):				•
FACILITY: WRANC		DEPT/SVC: Hemat	ology/	Oncology- Dept. Of Med.	-
ACCUMULATIVE PEDO	ASE Cost: Acc	CUMPLATIVE CONTRACT	Cost:	ACCUMULATIVE SUPPLY COST:	•
	CONTRACT COST:		DATE OF FINNUAL	COMMITTEE APPROVAL DA PROGRESS REPORT FEB 2.5 1983	- }
Ainsengne Chlcesidue BCG) CC PROGRESS BURING F Study closed eloped AML &	rambucil. Adde NU, UBN, Proc, Y-82: tozoticin 12/81. 6 pt's. expired.	endum #6 discont PRED, (IMER) ((IMER) exam o	tinued. compare of cont	ddendum #5 ,discontinued MER (Methanal extractab d to BLEO. ADRIA,VCN, St ribution of MER. o this date, 5/6 are in	ole reo-
Mumber of Subject					
FY-82 <u>: 0</u>	TOTAL (TO	DATE): 6	Befo	RE COMPLETION OF STUDY: Clos	ed
	D Side Effects in ient developed		riiig in P	ROJECT(IF NONE SO STATE):	-
CONCLUSIONS: pr between chemot			dicates	no significant differer	- nce
PUBLICATIONS OR A	BSTRACTS, FY-82:				-
NONE					

DATE: 10/2/82 NORK UNIT I	o.: 1539	SIATUS: 1	KTERIM	Firm X	-
STARTING DATE:	DATE OF	COMMITTION:	9/81		-
	anf Immunotherapy i				
HITLE OF PROJECT: CALGB: 754 previously untreated Sta	41: Combination Che age III and IV Neur	motherapy oblastoma	and Immuno	otherapy i	n -
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss.	M.D.			_
ASSOCIATE INVESTIGATOR(S):					
FACILITY: NRAYC	DEPT/S'C: Hema	tology/ Or	ncology - I	ept. Of M	<u>e</u> d.
ACCUMILATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Cost: Ac	CUMULATIVE SU	PPLY COST:	_
FY-83 NECCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COM ANNUAL PROS	MITTEE APPROVI RESS REPORT	FEB 25 198	_ <u>9</u> _
STUDY USJECTIVE: To evaluate phamide, and Adriamycon III and IV neuroblastoms TECHNICAL APPROACH: Vincrist Cyclophosphamide, Adriamycon PROSRESS DURING FY-82: Only cause of prior therapy 4 have all expired. This MUMBER OF SUBJECTS STUDIED:	tine, Cyclophospham iamycin, And MER. patients have bee and therefore tak is now closed. WR	herapy in famous logs ide, adriant n entered en off sta	previously ical respondance amycin, Vs.	y untreate nsiveness . Vincrist	d Stage .of -SEE ine below -
FY-82: 0 TOTAL	(TO DATE):	BEFORE C	CMPLETION OF	STUDY: CLOS	ED
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPAT	ING IN PROJE	CT(IF NONE SO	STATE):	
CONCLUSIONS: WRAMC date of shows both regimens to be	too sparse to formu	late any (conclusions	s. CALGB	 data
PUBLICATIONS OR ABSTRACTS. FY-	82:				
1	NONE				
Study Objective cont	inued: Patient to and during	s with d	isseminat	ted neuro	o-

DATE: 10-2-82	HORK UNIT NO.:	1543	STATUS	: INTERIM	x First	·
STARTING DATE: 1	1/2/0/81	DATE OF	COMPLET	10N: 10/	79	
KEY KORDS: Lymph	ocytic Lympl	noma				
		l - Combination of Adults with our				111 and
PRINCIPAL INVESTIG		ymond B. Weiss.	M.D.			
ASSOCIATE INVESTIG	ATCR(S):	D (C)	1 /			
FACILITY: WRAYC		DEPT/Syc: Hemate		Uncology	Dept. (of Med.
Accumulative PEBCA	SE Cost: A	CCUMULATIVE CONTRACT	Cost:	t .	IVE SUPPLY (Cost:
00 FY-83 FEDCASE: 00	CONTRACT COST:	SUPPLY COST:	DATE OF	COMMITTEE PROGRESS REP	PROVAL OF	5 1983
Lymphoma by add the role of rad TECHNICAL APPROACH tengrin Img/m2/mg/m2/po/x6wks PROGRESS DURING FY 15 patients er entry since 10 liumsar of Susjects FY-82: O Serious/Unexpected	ling Strepter liotherapy to li Chemotherapy wk/ po/ x 6 Maintance R' -82: Cytoxan litered at WR 0/79. 3 pt's STUDIED: 2 a	. are alive with re lost to follo logistical problo DATE): 15	tine, its. Str ine lmg s to bu nd Pred This r no ev w-up. BEFO	and Predn n improvi ep and d /m2/iv/6 ilky sites nisone or rotocol h idence of has been	isone. Tong remissuration wks., Prefollowed only CVI as been disease. I taken on	examine aion rate ednisone 40/ d by (CVP) R. closed to patient 9 have expired ff study due : Closed
CONCLUSIONS: At N	VRAMC, there	is a 50% remiss n to be of signi	ion res	sponse rat toxicity	e with the following	has therapy. g chemotherapy.
PUBLICATIONS OR AB	STRACTS, FY-82:		_			

None

DATE: 10/2/82 HOSK LINET	No.: 1546	STATUS: INTERIM X FIRM	-			
STARTING DATE: 7/27/77 BATE OF COMPLETION: 7/16/79						
KEY KORDS: Acute Lymphocytic Leukemia						
TIME OF PROJECT: CALGB: # 7611 - Treatment of Acute Lymphocytic Leukemia in patients under twenty.						
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss, M	1.D.				
ASSOCIATE INVESTIGATOR(S):	····					
FACILITY: HRAYC	Depr/Syc: Hemato	logy/ Oncology- Dept. Of Med.	, 			
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:	-			
00	00	00 ·	-			
FY-83 I'EDCASE: CONTRACT CO		DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2.5. 198	3.			
STUDY <u>OBJECTIVE</u> : To test whether High dose Methotrexate can substitute for cranial irradiation in decreasing the incidence of CNS Leukemia. To test whether consolidation with high dose Metho can increase the duration of RM. TECHNICAL APPROACH: Induction with Vincristine and prednisone and L- Asparaginase 50% of patients will receive high dose Methotrexate 500mg/m2x3 during consoliadatin,						
PROGRESS DURING FY-82: No patients entered in 1982. Of the 4 patients one remains in CR and is followed at WRAMC, two patients in CR were Transferred to other institutions and are lost to follow - up the last patient voluntarily stopped						
Number of Subjects Studied:[HUMBER OF SUBJECTS STUDIED: [maintance therapy and went off study and subsequently relapse.					
FY-82: 0 Total	L (TO DATE): 7	BEFORE COMPLETION OF STUDY: Close	<u>∙</u> d			
SERIOUS/UNEXPECTED SIDE EFFECT Severe Mucositi		THIS IN PROJECT(IF HOME SO STATE):	- .			
Conclusions: Protocol is	closed. Conclusions	s same as 79-80-81 .	-			

PUBLICATIONS OR ABSTRACTS, FY-82: Voorheis, et al : effects of difference forms of CNS proplylaxis on pituitary function of children with ALL. ASCO abstract 1981. F-reeman, et al comparison of intermediate dose MTX with Crainal radiation in children with ALL. Abstract ASCO, 1981.

Date: 10-2-82 Mass Eyes No.: 1547	Status: latering Fine X
STARGING Pare: 11-1-76 Bare (- (op 1110: 2-1-80
YEY LORDS: Metastatic Breast Cancer - Cher	otherany.
TITLE OF PROJECT: CALGB # 7682 - Combination	
Immunotherapy For Metastatic Recurrent Or	Inoperable Carcinoma of The Breast.
Paincipal Issasticator(s): Raymond B. Weiss,	M.D.
Associate levestigator(s):	
FACILITY: MAYO DEPT/Syc. Hemat	alogy/Oncology - Dept. Of Med.
Accumulative MEDCASE Cost: Accumulative Contract O Q	Cost: Accumilative Supply Cost:
FY-83 PECCASE: Contract Cost: Supply Cost:	DATE OF COMMITTEE APPROVAL DE L'ANDIAL PROGRESS REPORT FEB 2 5 1983
STUDY OBJECTIVE: To compare remission inductive CAF, CMF, and CAFVP combinations.	tion frequencies and duration of
CCHRICAL FORMACH: Prior to randomization for according to dominance of metastatic area develop either less than one year from dia	or treatment, patients will be stratified visceral Osseous soft tissue which
Pagazess Bustus FY-S2: [one year from diagnos:	is.
Of the 12 patients entered at WRAMC, one of the progressing . 10 have expired.	still remains free of disease,
Tis progressing, 10 have expired. Normatt of Suburcis Studied:	
FY-82: 2 TOTAL (TO DATE): 12	BEFORE COMPLETION OF STUDY: 20
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPA NONE	THIS IN PROJECT(:F HORE SO STATE):
Conceditions: CAF and CAFVP prolonged survival	as compared to CMF. No difference
between CAF and CAFVP arms . MER was of no	benefit.

PUBLICATIONS OR ABSTRACTS, FY-S2:

Aisner, J. et al , Frequency and Duration of Response with Combination Chemotherapy for metastatic Breast Cancer.

ASCO Vol. 20-1979.

DATE: 10/2/82	HORK ENIT N	o.: 1551		STATUS	! INTERIM	<u> </u>	FINAL
START ILE DATE:	8/1/76	8/1/76 DATE OF COMPLETION: 9/29/80					
KEY WORDS: AC	ute Lympho	cytic Leuk	emia				
Time of Project: in Adults.	CALGB: #	7612 - Th	erapy of	Acute	Lymphocyt	ic	Leukemia
PRINCIPAL INVESTIG	GATOR(S): R	aymond B.	Weiss,	1.D.			-,
ASSOCIATE INVESTIG	GATOR(S):	 -					
FACILITY: WANC		DEPT/S	WC:Hemat	ology/ (ncelogy -	De ₁	pt. Of Med.
Accumulative PEOC		ACCUMULATIV	re Contract	Cost:	Accumulati 00		UPPLY COST:
FY-83 FEDCASE:	CONTRACT COST	T: SUPPLY (0 0	OST:	DATE OF ANNUAL	COMITTEE PROGRESS REP	PPROP PGRT	FEB 2 5 1983
STUDY OBJECTIVE: T Prednisome for response. For TECHNICAL APPROACH po x 21 day	ollowed by determine :Regimen l L-Asparag	Asparagina if MER wi : Vincris ginase 500	ase will 11 incre tine 2mg mg/m2 IV	improve se rem /IV weel daily :	frequences from dure x 3 , Prox 3 , Pro	y ar rational redn	nd duration on. isone 40mg/m2 day 1-3).
PROSRESS DURING FY have expired, ission.	(-82: Study , 2 pts. lo	Closed Seport of fol	pt. 1980 low-up a	. Total nd 2 pt	of 16 pats. remain	tien in	ts entered, 12 complete rem-
Number of Subjects	ಽ ಽ೯೮೦(ಎ:						
FY-82 <u>: 0</u>	Total	(TO DATE):	16	BEFOR	RE COMMETTO	or of	STUDY: Closed
Serious/Unexpected NONE		s им Ѕиви́встѕ	PARTICIPA	rins in P	POURCT (IF THO	one so	STATE):
(Daunomycin) 16 months wit	superior	to Vincri	benefi stine/Pr	t. Addi ednison	tion of Are alone.	ntra Med	cycline ian survival
PUBLICATIONS OR AB	ISTRACTS, FY-S	2:					

DATE: 10/2/82 HORK UNIT N	o.: 1 552	STATUS: INTERIM	X First
STARTING DATE: 11/30/76	DATE OF	COMPLETION:	-
KEY KORDS: CLL		•	
TITLE OF PROJECT: CALGB: #	7632 - Chemotherap	y in Indolent CL	L
			
PRINCIPAL INVESTIGATOR(S): E	Raymond B. Weiss, M	.D.	
ASSOCIATE INVESTIGATOR(S):			
FACILITY: KRANC	Dept/Syc: Hemat	ology/ Oncology	- Dept. Of Med.
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Cost: Accumulati	VE SUPPLY COST:
00	00	00 ·	
FY-83 I'EDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE AS ANNUAL PROGRESS REPO	PROVAL OF
	00	FANNUAL PROGRESS KEP	ORT FEB 2 5 1983
STUDY OBJECTIVE: To determ CLL will prolong survival TECHNICAL APPROACH: After in	1.		
domized to Regimen 1: No 0.5mg/kg po q 28 days.	treatment, or regi	men II : intermi	ttent Chlorambu
PROGRESS DURING FY-82: To dat	te 3 patients have	been entered. L	patient experi-
enced progressive disease	e and was removed f		
patients are alive with a Mummer of Suspects Studged:	stable disease.		
_			
FY-82: 0 TOTAL	(TO DATE): 3	_ BEFORE COMPLETION	OF STUDY: unk
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	S IN SUBJECTS PARTICIPAT	THE IN PROJECT(IF NO	E SO STATE):
CONCLUSIONS:			
100 early for	r this indolent dis	ease.	
,			
•			
PUBLICATIONS OR ABSTRACTS. FY-8	32:	·	
INONE			

_	DATE: 10-2-82	HORK UNIT No.:	1 558	STATUS: INT	TERIM X	Fire.	_
_	STARTING DATE: 1	977	DATE OF	COMPLETION:	12-81		_
•	Key Koros Primary	treatment of	Mulitple Myelo				-
multi multi	Time of Project: the alkylating ple Myeloma.	CALGB + 7761 agents with	- A study to d or withour Adri	etermine th amycin in t	ne effect the prima	tiveness of ary treatmen	single vs. it of
v	PRINCIPAL INVESTIG	GATOR(S): Ra	vmond B. Weiss.	M.D.			
	ASSOCIATE INVESTIG						-
-	FACILITY: VRANC		Dapr/Svc: Hemat	ology #Onco	logy , I	ept. Of Med	<u>l</u> .
•	Accumulative MEDC	ASE Cost: Ac	CUMULATIVE CONTRACT	Cost: Accu	MULATIVE :	SUPPLY COST:	•
•	FY-83 PEDCASE:	CONTRACT COST:	Supply Cost:	DATE OF COMMI FAMUAL PROGRE		FEB 2 5 198	3
ially than	STUDY OBJECTIVE: produce, high the same alky	To test the her frequency ating agents	ypothesis that of good respons given in comb.,	three alkyle and longe that addit	ating ag r durati	ents given on of disea driamycin t	: sequent= use control, io a comb.
		of three	alkylating agen the duration o intravenous L	ts,increase	s the fi	requency of	good res-
-	PROGRESS DURING FY		ents put on stu	·			•
2 co	mplete remission	on, 5 partial	remission, 4 s	table disea	se , 4 d	eaths.	
-	Munaer of Subjects	STUDIED:					-
	FY-82 <u>: 0</u>		DATE): 15	BEFORE COM	PLETION OF	: Sтиру <u>: 15</u>	-
•	SERIOUS/UNEXPECTED NONE		SUBJECTS PARTICIPAT	ING IN PROJECT	(IF NONE S	SO STATE):	•
-	CONCLUSIONS: NOne	at this time					-
			•				
-	PUBLICATIONS OR AS	STRACTS, FY-82:					-
	NONE						
1	Technical Appone: L-Pam.	eroach: Co	mbination alk	ylating a	gents	plus predm	n i –
	uxenc	o vius pred	018000 1 = Dam	C ** * 1 L	1		
-	one: L-Pam	cycrosphos	phamide and B	CNU versu	s L-Pai	m plus pre	dni-

	DATE: 10-02-82 Mark UNIT No.:	1559	STATUS:	INTERIM	First x	<u>-</u>
	START 1:3 DATE: 09-01-77	DATE O	F COMPLETI	on: 1980		-
	KEY NOPOS: Small. Cell car			<u> </u>	·	_
	TITLE CF PROJECT: CALGB+ 7781 dosease/	- Small cell ca	rcinoma	of the Lun	g Localized	
	PRINCIPAL INVESTIGATOR(S):R	J. D. Wataa	м п			-
	ASSOCIATE INVESTIGATOR(S):	aymond B. Weiss,				-
•	FACILITY: WRANG	DEPT/Svc: Hen	atology,	/ Oncology	, Dept. Of M	ed.
		ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE	SUPPLY COST:	•
	FY-83 MEDICASE: CONTRACT COST:	00 Supply Cost:	Bors os	Countries (20)	20141 D=	-
	_0000	00	FANUAL F	ROGRESS REPOR	ROVAL 0F FEB 2 5 198	3
•	Study Objective: To determine	whether CCV/AV	plus rad	iio ther apy	(RT) gives a	r greater
re 1a	mission rate and duration tion increases response an	than MACC plus R	T. To de	etermine if	MER immunos	timu—
	TECHNICAL APPROACH: Regimen 1:	Methotrexate 30	mg/m2/IV	V plus Adria	amycin 35mg/m	m2 VS.CCNu
30mg/ Vincr	m2 plus Cyclophosphamide 4 ittine 1.0mg/m2 with Adria	mycin_50mg/m2/TV	_day_21_	with vince	istine 1.0mg	m2/IV.Both
WRAMC	PROGRESS DURING FY-82: [regime has entered 21 pts.whole has	ns include 4500	rads to	primary lu	ng tumor plu	s 3000 rads
	te. This protocol was close	ed 6/81. All pt.	sat this	point have	e expired ex	cept 2. who
	Number of Subjects Studied: [are	alive and show follow-up and as	no evide	ence of disc expired due	ease and 2 w to their ad	ho are lost to vanced disease
	FY-82: 0 Total (1	follow-up and as 0 DATE): 21	BEFOR	E LUISTELLON (OF STUDY: CLOSE!	state.
•	SERIOUS/UNEXPECTED SIDE EFFECTS I	N SUBJECTS PARTICIPA	fing in p	project NONE	SO STATE):	-
•	NONE		•	· · · · · · · · · · · · · · · · · · ·		-
	Complete remiss of cases. MER does not see	sions can be att	ained bu	it in a very	small perce	entage
	· · · · · · · · · · · · · · · · · · ·	and to be or vara	.			
	PUBLICATIONS OR ABSTRACTS, FY-82:					_
	TOPLICATIONS OF LESSINGIST TOP					

NOne

,	DATE: 10-02-82 HORK LINIT No.: 15	560 S1	ATUS: INTERIM	Frise X	•
	STARTING DATE: 10-77	DATE OF COM	PLETION: 03-8	<u>l</u>	_
	KEY WORDS: Small cell Cancer of	Lung Extensive			<u>-</u>
	TITLE CF PROJECT: CALGB # 7782 - S	Small Cell Carc	inoma of Lung in	Extensive I)i s ease.
				·	_
	PRINCIPAL INVESTIGATOR(S): Ray	ymond B. Weiss.	M.D.		_
	ASSOCIATE INVESTIGATOR(S):	·			_
	FACILITY: WRANC D	EPT/Svc: Hematolo	gy/ Oncology De	pt. , Dept.	Of Med.
	ACCUMULATIVE MEDCASE COST: ACCUMU	LATIVE CONTRACT COST	: ACCUMULATIVE	SUPPLY COST:	;
	00	.00	00	-	•
	FY-83 FEDCASE: CONTRACT COST: SUPP	PLY COST: DAT	E OF COMMITTEE APPROUAL PROGRESS REPORT	FEB 2 5 198	3
•	STUDY USJECTIVE: To determine who	ther alternation	g chemotherapy	increases re	: esponse
rat	e or duration. To determine whe	ther radiothera	py to primary to	umor increas	es response
rac	e over MACC chemotherapy alone. TECHNICAL APPROACH:	ersus MACC - ve	reue COACC	······································	
	PAGE 1 KI. V	eraus intoo - ve.	add corror.		
	PROGRESS DURING FY-82: To date a to	otal of 14 patie	ents have been e	ntered. Of t	hose
14 bei	patients all have expired. This ng followed. This is a finalize	s protocol is no	w closed. No fu	rther patien	its are
	Number of Subjects Studied:				
	FY-82: O TOTAL (TO DATE	<u>:): 14</u>	BEFORE COMPLETION OF	STUDY: CLOSE	Ø
	SERIOUS/UNEXPECTED SIDE EFFECTS IN SUB.	JECTS PARTICIPATING	IN PROJECT(IF NONE S	STATE);	,
-	None	<u> </u>			
	CONCLUSIONS: Survival of these	patients is not	significantly o	different wi	th ·
d1f	ferent treatment arms. Survival	of this group	os less then 1%	•	
_					
•	Publications Co Abstracts, FY-82:				•
	NOne				

DATE: 10-2-82 HOSK UNIT N				X Fire	- -
STARTING DATE: 1977	DATE OF	COMPLETION:	<u> </u>		-
Key logges: Hodgkin's Die	sease				_
TITLE CF PROJECT: CALGB: 7				eness of Comb	
Chemotherapy alone and with/ poor risk patients with Stag	kadiation therapy by e 1 or 11 Hodekins (iisease.	d liela	or extended	. ileid, in
					_
	Raymond B. Weiss, M	•D•			-
ASSOCIATE INVESTIGATOR(S):					-
FACILITY: WRANG	DEPT/SVC: Hemato	logy/ One	cology ,	Dept. Of Med	<u>l.</u>
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT C	ost: Ac	CUMULATIV	E SUPPLY COST:	-
00	00		<u> </u>		-
FY-83 I'EDCASE: CONTRACT COS	T: Supply Cost:	DATE OF COM ANNUAL PROS	MITTEE AP BRESS REPO	PROVAL 0= 2 5 198	- }3
STUDY OBJECTIVE: To determinand less toxic than cheme TECHN:CAL APPROACH: Regimen Vinblastine, Procarbazine, a 11 (2/12/79 delet the arm with Procass During FY-82: WRAM entered 13 patients in 1	l: Involved field nd Prednisone, Riegoth extended field R. C does not enter pa	ved field RT follow men 11: (radiat wed by s Themothe	ion. ix cycles of rapy alone. A	CCNU.
FY-82: 0 TOTAL	(TO DATE): 13	_ BEFORE C	COPLETION	of Study: None	at WRAMC
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	S IN SUBJECTS PARTICIPATIO	ECORP IN DE	CT(IF NON	E SO STATE):	- .
CONCLUSIONS: Too early 6	or analysis.				-
•					
Fu d	22				_
PUBLICATIONS OR ABSTRACTS, FY-8)Z;				

DATE: 10/2/82 Nox UNIT IN	o.: 1564	STATUS: INTERIM	Fire X			
STARTING DATE: 7/78 BATE OF COMPLETION: 7/81						
Key Moras: Chlorozotocin						
TITLE OF PROJECT: CALGE # :	7772 - Phase II s	tudy for Chloroz	otocin			
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss, N	I.D.				
ASSOCIATE INVESTIGATOR(S):						
FACILITY: HRANC	DEPT/Syc: Hemato	logy/ Oncology -	Dept.fo Med.			
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Į.				
FY-83 I'EDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE AS				
00 00	00	ANNUAL PROGRESS REPO	RT FEB 2 5 1983			
[caus	tocin 120mg/m2 q 6 dd of 30 seconds vi	weeks. The drug of a the tubing of a response followed to do the d	will be administ- a running owing the			
MUMBER OF SUBJECTS STUDIED:						
FY-82: 0 TOTAL	(TO DATE): 18	_ BEFORE COMPLETION	of Study: closed			
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	S IN SUBJECTS PARTICIPAT	ING IN PROJECT(IF NON	E SO STATE):			
CALGB , experience is	e of the patients that Chlorozotoci	responded. All han is questionable	ive expired.			
PUBLICATIONS OR ABSTRACTS, FY-8	32:					
NONE						

Progress during FY-82: Protocol closed 7/81. WRAMC entered 3 patients this year. Of the total number of patients entered to date (18) all have expired. One patient was transferred to Ft. Benning and is now lost to follow-up and assumed expired also due to extent of his disease. This is a finalized report.

DATE: 10-2-82	HORK UNIT NO .:	1570	Status	: INTERIM X	Fire	
STARTING DATE:	4/30/79	DATE	OF COMPLET	TION:		
Key Koras: Hist	iocytic Lymph	noma				
TIME OF PROJECT:	CALGB: 7851 -	- Treatment o Lymphoma.	f Advanc	ed Diffuse Hi	stiocytic	
PRINCIPAL INVESTIG	PATOR(s): Raymo	ond B. Weiss.	M.D.			
ASSOCIATE INVESTI	GATOR(S):					
FACILITY: HRAYC		DEPT/Svc: Hem	atology/	Oncology- De	pt. Of . Med	١.
ACCUMULATIVE PEDC	ASE Cost: Ac	CUMULATIVE CONTRAC	T Cost:	ACCUMULATIVE S	SUPPLY COST:	
00		00	T D	00		
FY-83 I'EDCASE: 00	CONTRACT COST:	SUPPLY COST:	PANHUAL	COMMITTEE APPROPRIES REPORT	FEB 2 5 1983	
crease the responding PREDNISONE. (Cr	onse rate and nop) test con [in particular [system re]	lasoe.	yclophos igh dose t is pro	phamide, Vinc Methotrexate phylactic aga	eristine,Adri e to above pr ainst central	amycin cogram nervous
PROGRESS DURING F	<u>/-82</u> : 5 pt.'s od partial re	have been entermission or com	ered at i	WRAMC all thremission.	ee are doing	well,
HUMBER OF SUBJECTS	: Sדעסובּם:					
FY-82: a	TOTAL (TO	DATE): 5	Befo	RE COMPLETION OF	STUDY: 320	
Serious/Unexpected NONE	SIDE EFFECTS IN	SUBJECTS PARTICIP	ATING IN P	ROUECT(IF NONE S	STATE):	
Complusions: To adquate thera	date , it app py in that re	ears that treamission are in	itment wi	th CHOP and lid toxicity is	Bleomycin is s minimal.	
PUBLICATIONS OR AS	STRACTS. FY-82:		 			
NONE						
Technical Ap	proach: Ti	reatment cat	egorie	s expanded	to other	
poor histolo Bleomycin ir	fusion X 3	courses wit	erapy w h rand	with and wi omization f	thout cont ollowed by	inuous

standard or high dose Methotrexate.

DATE: 10/2/82 Mask Unit Its	o.: 1572	STATUS: INTERIM X	Fitter.
STARTING DATE: 5/79	DATE OF	COMPLETION: 4/81	
Key Meas: M-AMSA, Mela	noma, Ovarian Carc	inoma, Breast Carci	noma.
TITLE CF PROJECT: CALGB :# for Melanoma, Ovarian Ca	7971 - Phase II St	udy of M-AMSA, (NSC	249992) Treatment
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss,	M.D.	
ASSOCIATE INVESTIGATOR(S):			
FACILITY: MRAYE	DEPT/Syc: Hem	atology/ Oncology -	Dept.Of Med.
Accumulative MEDCASE Cost:	ACCUMULATIVE CONTRACT	Cost: AccumuLative S	SUPPLY COST:
00 FY-83 FEDCASE: CONTRACT COST 00 00	00 T: SUPPLY COST: 00	DATE OF COMMITTEE PAPER FAMULAL PROGRESS REPORT	PEB 2 5 1983
plete or pattial responsement with M-AMSA. Determ TECHNICAL APPROACH: The first dose will be increased by until Myelosuppression is Progress During FV-82: 8 pat 2 are alive with disease	s encountered. ients have been en	tered at WRAMC , 4	
Number of Subjects Studied:			
FY-82: 0 TOTAL	(TO DATE): 8	BEFORE COMPLETION OF	: Stuby: 162
SERIOUS/UNEXPECTED SIDE EFFECT	s in Subjects Participa	TING IN PROJECT(IF NOME S	SO STATE):
Conclusions: Date is spa of RX.	rse. 50% of patien	t entries have died	within a year,
PUBLICATIONS OR ABSTRACTS, FY-	82:		

DATE: 10/2/82 NOW UNIT TO	o.: <u>1574</u>	STATUS: INTER	M Final v
STARTING DATE: 12/12/79	DATE OF	COSTETION:	10/82
Key Nors: Gastric Cancer	·		
Title of Project: CALGB: #79 or Metastatic Gastric Car			n locally Advanced
PRINCIPAL INVESTIGATOR(S): p ASSOCIATE INVESTIGATOR(S):	Raymond B. WEiss,M.	D	
FACILITY: MRAYC	DEPT/SVC: Hemato	logy/ Oncolog	y -Dept.Of Med.
Accumunative PEDCASE Cost:	ACCUMULATIVE CONTRACT (OST: ACCUMUL	ATIVE SUPPLY COST:
FY-83 PEDCASE: CONTRACT Cos	T: Supply Cost:	DATE OF COMMITTE	E PPROVAL 0-2 5 1983
two drug combination, exc disease progression when TECHNICAL APPROACH: Regime Regime PROGRESS DURING FY-82: Four 4 have expired. This pro	n A-5 - Fluorouraci n B-Mitomycin-C and patients have been	l , Mitomycia Adriamycia.	n-C and Adriamycin belo
Howser of Subjects Studied:			<u> </u>
FY-82: 0 TOTAL	(TO DATE): 4	_ BEFORE COMPLE	TION OF STUDY: Closed
SERIOUS/UNEXPECTED SIDE EFFECTS	s in Subjects Participati	ng in Project(15	HONE SO STATE):
Two patients devolpe	ed transient signfi	cant Pancyton	enias.
Conclusions:	s too few patients		
· ·			

Study Objective: (continued) patients, 2. to determine partial and complete response frequency, and the duration of response and survival of patients with measurable, locally advanced, or with metastatic gastric cancer, when the patients are treated with MA versus FAM and both regimens are followed by a common maintenance therapy employing Mitomycin -C and 5-Fluorouracil.

DATE: 10-2-82 HOSK UNIT N	o.: 1575	STATUS:	INTERIM	X Fribi	
STARTING DATE: 1979		COMPLETE	ON:		
	odgkins Disease 972 - A phase 11 t c Lymphoma and dif	rail of	AMSA for	refractory erentiated	Hodgkins Lymphocytic
mphoma.					
PRINCIPAL INVESTIGATOR(S): ASSOCIATE INVESTIGATOR(S):	Raymond B. Weiss,	м.р.			
FACILITY: WRANC	DEPT/SVC:Hemato	logy/ C	ncology -	Dept. Of M	ed.
Accumunative MEDCASE Cost:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATI	VE SUPPLY COST	• • • • • • • • • • • • • • • • • • •
00	00		0.0		
	T: SUPPLY COST:	Date of Annual F	COMMITTEE P ROGRESS REP	PPROVAL OF ORT <u>FEB 25</u>	<u>1983</u>
with Hepatic dysfunction PROSESS BURING FY-82: [Myelonly 8 patients have been and 1 is lost to fowwow-up humber of Sususcis Studies:	entered. 4 patien	countere ts have	expired,	3 are alive	with disease
FY-82: 0 TOTAL	(TO DATE): 8	Befor	RE COMPLETIO	יי אפטדא גס אנ <u>ט: ר</u>	losed
Sarious/Unexpected Side Effect Increased interval				DNE SO STATE):	
Conceusions: Data too span	rse for for formul	ation of	any cond	clusions.	
PUBLICATIONS OR ABSTRACTS, FY-	S2:				
NONE					

DATE: 10/2/82 HORK BUIT NO	o.: 1576	STATUS: INTE	RIM FIRE X
STARTING DATE: 8/79	DATE O	F COMPLETION:	9/81
Key Nords: Pancreatic Car	ncer		
TITLE OF PROJECT: CALGB:#	7982 - Chemotherap	y of Advance	d Pancreatic Cancer,
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss,	м.р.	
ASSOCIATE INVESTIGATOR(S):			
FACILITY: KRAYC	DEPT/Svc: Hemat	ology /Oncol	ogy - Dept. Of Med.
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT	Cost: Accum	
	00 T: SUPPLY COST: 00	DATE OF COMMIT	TEE PPROVE TEB 2 5 1983
STUDY OBJECTIVE: Establish a Cancer. TECHNICAL APPROACH: Reg. 1 5F Reg. 2: 5		and MItomyci	n C.
PROGRESS DURING FY-82: 3 Pati three have expired. This	ents had been ent is a finalized re	ered prior to	protocol closure. A
MUMBER OF SUBJECTS STUDIED:			
FY-82: 0 TOTAL	(TO DATE): 3	Before Copp	LETION OF STUDY: Closed
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	IN SUBJECTS PARTICIPA	тив и Развет(IF NONE SO STATE):
CONCLUSIONS: Data too spar	se to formulate a	ny conclusion	S.
PUBLICATIONS OR ABSTRACTS, FY-8	2:		
NONE			

	DATE: 10/2/82 MORK UNIT NO	0.: 1577	STATUS	INTERIM X	Final	
	STARTING DATE: 1/20/80	DATE OF	COMLET	101: 1982	····	
	KEY KORDS Acute Myleogenous	Leukemia				
	TITLE OF PROJECT: CALGE:# 79 regimen and two maintance)21 - Comparative > regimens in Acut	study o	genous Leuke	mia,	.on
	PRINCIPAL INVESTIGATOR(S): RE	aymond B. Weiss, M	I.D.			
	ASSCRIATE INVESTIGATOR(S):		·			
	FACILITY: WRANC	DEPT/Syc:Hemato	logy /	ncology - De	pt. Of Med.	
	Accumulative PEDCASE Cost:	ACCUMULATIVE CONTRACT	Cost:	AccumuLative S	SUPPLY COST:	
	FY-83 PECCASE: CONTRACT COST	T: SUPPLY COST:	DATE OF FANUAL	Committee Appar Progress Report	PAL 0= EEB 2 5 1983	
5/	STUDY OBJECTIVE: 1. To determine willing rease the remission in infection rate during TECHNICAL APPROACH: Randomi Regimen B without Co- Tr. (DNR) 45mg/m2 IV days 1, PROSRESS DURING FY-82: To date 13 in CR and being active	on rate. 2. To detremission induction zed: Regimen A wifinaxazole. Randomi 2,3 and ARA-C 100 to a total of 13 p	ermine th CO ze bei mg/m2	if Clotrimox Trimoxazole p ween regimen V by contino	oo during indu	uction.
	MUMBER OF SUBJECTS STUDIED:					
	FY-82: 3 TOTAL	(TO DATE): 13	Befor	RE COMPLETION OF	: Study: 550 CA	LGB
,	SERIOUS/UNEXPECTED Side Effects One patient devel	in Subjects Participat Loped actual Hepat				
tı	CONCLUSIONS: After 230 paticeatment and opinion exist	ents entered have	been e	valuated, no	trend toward	
	PUBLICATIONS OR ABSTRACTS, FY-8	2:	NO	ONE		
	Technical Approach: IV day 1, plus 6 th	continued: Reg 2,3 + ARA-C 100 ioguanine 100 m	mg/m	2 by contin	IR 45 mg/m2 nuous infus	ion

DATE: 10-2-82	HOSK BHIT IK	.: 1578	STATUS	INTERIM Y	Firal	
STARTING DATE: 7	-80	DATE OF	COMPLET	ION: 1983		
Key logos: Chemo	therapy -	Metastatic Breast (lancer		~	
TITLE OF PROJECT: Hormanal Thera of Advanced Br		081 A Randomized S motherapy with Chem r.	tudy (nothera	Comparing The ipy alone For	Combination The Treatme	of nt
PRINCIPAL INVESTIG		aymond B. Weiss, M.	.D.			
ASSOCIATE INVESTIG	ATOR(S):					
FACILITY: HRANC		DEPT/Svc: Hemata	logy/	ncology - De	pt. Of Med .	
Accumulative PEDCA	SE Cost:	ACCUMULATIVE CONTRACT (Cost:	ACCUMULATIVE S	UPPLY COST:	
FY-83 PECCASE:	CONTRACT COST	T: SUPPLY COST:	DATE OF FINNUAL S	Committee Appro Progress Report	VAL 07 FEB 2 5 1983	
		ne effectiveness of plus Hormanal the				
TECHNICAL APPROACH	Reg L: C	AF + TamoTamoxifen CAF				
	alive wit	1 of 13 patients no h progressive diseanses.				
NUMBER OF SUBJECTS	: בומטז					
FY-82 <u>: 5</u>		(TO DATE): 13				300 30
SERIOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PARTICIPATI	irig in Pr	ROJECT(IF NONE S	STATE):	
NON			·		····	
Conclusions: Study	y is open,	active and accurin	ng pati	ents . No Co	nclusions so	far.
PUBLICATIONS OR AB	STRACTS, FY-8	2:			· · · · · · · · · · · · · · · · · · ·	

STARTING DATE: 1979	· · · · · · · · · · · · · · · · · · ·	COMLETIONS	03-82	F100s_ X	- -
Key Nords: Gastric Adenoca	rcinoma				_
Adriamycin, and Mitomycin					
PRINCIPAL INVESTIGATOR(S): Ray	mond B. Weiss, M.I				-
ASSOCIATE INVESTIGATOR(S):					-
FACILITY: MRAYE	DEPT/SVC: Hemata	logy/Oncol	ogy ,Dept.	Of Med.	_
Accumulative PEOCASE Cost:	ACCUMULATIVE CONTRACT	Cosr: Acc	UMULATIVE SU	PPLY COST:	•
FY-83 FEDCASE: CONTRACT COST	r: Supply Cost:	DATE OF COMM ANNUAL PROGR	ITTEE PEPROV.	AL OF	· ·
Flououracil, adriamycin and mocarcinoma of the stomach		wing poten disease fr		ative sure	gery for
TECHNICAL APPROACH: Regimen louoeoueacil, Adriammycin a adenocarcinoma of the ston	mach produces a lourgical resection a	lone.)	n ll : Adj entially o val in com	uvant Cher urative su	nothera urgery
adenocarcinoma of the ston	mach produces a lourgical resection a	lone.)	n II: Adjentially o	uvant Cher urative su	nothera urgery
adenocarcinoma of the ston	mach produces a lourgical resection a	lone.)	n ll : Adj entially o val in com	uvant Cher urative su	nothera; urgery
No patients were entered No See Subjects Studied: FY-82: O Notate	nach produces a lourgical resection and an	WRAMC. BEFORE CO	WELETION OF	juvant Cher curative su aparision t	nothera urgery to stan
No patients were entered Humber of Subjects Studied:	nach produces a lourgical resection and an	WRAMC. BEFORE CO	WELETION OF	juvant Cher curative su aparision t	nothera urgery to stand
No patients were entered HUMBER OF SUBJECTS STUDIED: FY-82: 0 TOTAL SERIOUS/UNEXPECTED SIDE EFFECTS	nach produces a lourgical resection and an	WRAMC. BEFORE CO	WELETION OF	juvant Cher curative su aparision t	nothera urgery to stand
No patients were entered No Patients Were e	nach produces a loargical resection and a longical resection and a longical resection and a longical research and a longical r	WRAMC. BEFORE CO	WELETION OF	juvant Cher curative su aparision t	nothera urgery to stand

 						
DATE: 10-2-82 HOOK UNIT N	o.: 1581	STATUS: INTERIM X	Final.			
STARTING DATE: 3/79	DATE OF	COMPLETION:				
Key Noras: Lymphocytic Lym	mphoma Combination	Chemotherapy.				
Title of Project: CALGB: + poorly Differentiated	7951 - The Manageme	nt of Stage Ill an	d Iy Nodular			
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss,	M.D.				
ASSOCIATE INVESTIGATOR(S):		·				
FACILITY: MRAYC	DEPT/Syc: Hemato	logy/ Oncology- De	pt. Of Med.			
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	1	Supply Cost:			
FY-83 PEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPR ANNUAL PROGRESS REPORT	OVAL 0F FEB 2 5 1983			
STUDY OSJECTIVE: To compare efficacy of combination chemotherapy vs. single agent therapy and combination therapy chemotherapy. To compareresponse in patients treated with single agent comb. Chemo. in induction. TECHNICAL APPROACH: Regimen 1: Cytoxin 100mg/m2/day continously. Regimen 2: Cytoxin 759mg/m2/iv day 1. Adraimycin 50mg/m2/iv day 1. Vincristine 1.4mg/m2/iv/day 1. Bleomycin 10u/m2/im/day 1. Prednisone 60 mg/m2/po/day 1-5 PROSSESS DURING FY-82:5 patients have been entered. All in good partial remission. Possibly Complete remission.						
Murser of Subjects Studied:						
FY-82: 0 TOTAL	(TO DATE): 5	BEFORE COMPLETION O	.= Sτυρ <u>γ:</u> 75			
SERIOUS/UNEXPECTED Side Effects in Subjects Participating in Project(if none so state): NONE						
CONCLUSIONS: Not a great of partial remission. There	deal of data but, 5 efore , this treatm	of the 5 patients ent plan may be of	have experienced significent value.			
PUBLICATIONS OR ABSTRACTS, FY-82:						

DATE: 10.2/82	HORK UNIT NO.:	_1583	STATUS	: INTERIM	Final x
STARTING DATE: 5	/ 80	DATE	OF COMPLET	101: 9/81	-
Key Nords: Spi	rogermanium	in Advanced Co	lorectal	Carcinoma	···
TITLE OF PROJECT:		75 Spirogerman nt Colorectal			Advanced
PRINCIPAL INVESTIG		ymond B.Weiss,	M.D.		
ASSOCIATE INVESTIG	GATOR(S):	Dear/Suga Ho	matalogy	/ 0201000	-Dont Of Mod
FACILITY: WRANC				`	-DeptOf Med.
ACCUMULATIVE PEDC	ASE COST: I	ACCUMULATIVE CONTRA	ict Lost:	ACCUMULATIVE 00	E SUPPLY COST:
FY-83 FEDCASE:	CONTRACT COST:	Supply Cost:	DATE OF	COMMITTEE FOR	PROVAL OF RT FEB 9 5 1023
PROGRESS BURING F closed. This i	en 50mg/m2/I <u>Y-82</u> : 3 Pati	V 2x weeks; the ents entered.	en 50mg/r	n2/IV weekly	y •
Number of Suguect	s Studied:				
FY-82: 0	TOTAL (1	TO DATE): 3	Befo	DRE COMPLETION	OF STUDY: closed
SERIOUS/UNEXPECTED NO		IN SUBJECTS PARTIC	PATING IN F	ROJECT(IF NON	E SO STATE):
CONCLUSIONS: Dat	a too sparse	to formulate	conclusio	ons.	
PUBLICATIONS OR A	BSTRACTS, FY-82				

DATE: 10-02-82 HOPE ENET HO).: 1584	STATUS: INTERIM	
STARTILE DATE: 3/80	DATE OF	COMPLETION:	4/81
KEY NORDS: Multiple Myelo Time of Project: CALGB:# 80 Myeloma resistance to Me	074 - A phase II	trail of AMSA in	nisone Multiple
PRINCIPAL INVESTIGATOR(S): R ASSOCIATE INVESTIGATOR(S):	aymond B. Weiss, M	1.D.	
FACILITY: WRANC	Dept/Syc: Hemat	ology/ Oncology	-Dept.Of Med.
ACCUMULATIVE MEDICASE COST:	Accumulative Contract	00	
FY-83 PECASE: CONTRACT COST	T: SUPPLY COST:	DATE OF COMMITTEE P ANNUAL PROGRESS REP	PPROVAL OF 2 5 1993
STUDY OBJECTIVE: Determone Melphalm, and Prednisome TECHNICAL APPROACH: Provide G 3 weeks	other alkylating a	agents. xicity of AMSA -	- 120-mg/m2/IV -
PROGRESS DURING FY-82: This patients were ever ente	protocol was act	ivated and subquenalized report.	ently closed. No
HUMBER OF SUBJECTS STUDIED: FY-82: TOTAL SERIOUS/UNEXPECTED SIDE EFFECTS	(TO DATE): 0 S IN SUBJECTS PARTICIPA		ON OF STUDY: closed
NONE			
CONCLUSIONS:			
PUBLICATIONS OR ABSTRACTS, FY-	82:		
NONE.			

	DATE: 10-2-82	Hose Ever li	o.: 1585	STATUS	: INTERIM	Final X	_
	STARTING DATE:	12-80	DATE OF	CONCET	1011: 09-81	····	
	KEY HOPDS: AZO	in primar	y treatment of ext	ensive	lung cancer		_
	TITLE OF PROJECT:	CALGB: 804	46 AZQ in primary	treatm	ent of local	lly advances	or ex-
tens	sive cancer of	the Lung of	rhter than small co	ell, A	phase III st	tudy.	
	PRINCIPAL INVESTI	GATOR(s):	Raymond B. Weiss,	M.D.			_
	ASSOCIATE INVESTI	GATOR(S):					~
	FACILITY: WRANC		DEPT/Syc: He-ma	to logy	/ Oncology	Dept. Of M	[ed.
	ACCUMULATIVE PEDC	ASE Cost:	ACCUMULATIVE CONTRACT	Cosi:	ACCUMULATIVE	SUPPLY COST:	~
	00		00		00		~
	FY-83 MEDCASE:	CONTRACT COS	T: SUPPLY COST:	DATE OF	Committee Appe Progress Report	ROVAL OF FEB 2.5 131	3 5
thei 35i	TECHNICAL APPROACE re is no signifugm2IV PROGRESS DURING F	H: AZQ 30mg icant myelo Y-82: this p 10 patients oth surviva	m/m2IV intially. In protoce! was closed were entered. to all form dx to rx.	f on Da	y 7-14 (afterubsquent 3 v	er lst. dose	of AZQ) will be
	FY-82: 0		(TO DATE): 10	BEFO	RE COMPLETION O	DE STUDY <u>: CLOS</u>	<u>e</u> D
	SERIOUS/UNEXPECTED	D SIDE EFFECTS NONE	S IN SUBJECTS PARTICIPAT	Titis Iti Pi	ROJECT(1F NONE	SO STATE):	-
		oup wide ex d not see a	kperience was that	the dr	ug had some	activity bu	- it we
	PUBLICATIONS OR A	estancts FV-9	_श ्				
	LOBETCH LONG ON ME	531KMC137 1 1°C	<i>,</i>				
	NONE						

DATE: 10/2/82	HOSK UNIT HE	o.: 1586		SEATUS	: INTERIM	X	Final
STARTING DATE:	9/18/80		DATE C	F COYLET	10%:		
Kay Nogos: Acute	Lymphocy	tic Leukemi	а				
TITLE OF PROJECT: C	algb # 80	ll - A stu	dy of t	he effe	ctiveness		
ith two courses uction in adult						io 11o	wing remiss
		uce cympnoc	}	HAEUTA.			
PRINCIPAL INVESTIG	ATOR(S):	Raymond B	Weiss	, M.D			
ASSOCIATE INVESTIG	ATOR(S):						
FACILITY: HRANC		DEPT/SV	CHemato	logy/ (ncology -	- Dep	t. Of Med.
ACCUMULATIVE MEDICA	SE Cost:	ACCUMULATIVE	CONTRACT	Cost:	ACCUMULAT	IVE SU	PPLY COST:
00		0				0_	
		T: SUPPLY CO		DATE OF	COMMITTEE	yose⊊ł •	AL OF EB 25 1993
		00		7541022	1 110011200 112		ED 23 1443
TECHNICAL APPROACH PO dailey x 21 day 1 , Leukovo PROGRESS DURING FY relasped and p	orin 12mg/ -82: Only	m2/IV and $2m2/IV$ and $2m2/IV$ and 2	2,24, at	id 48hr	Post	MIX .	dintensific
Mumber of Subjects							
FY-82: 2	TOTAL	(TO DATE):		Befo	RE COMPLETI	0:1 0:=	STUDY: 800
SERIOUS/UNEXPECTED NONE	SIDE EFFECTS	s in Suauects I	Participa	ring in P	ROJECT(IF :	ione sa	STATE):
CONCERSIONS: Me	expect 6 p	atients to	be ent	ered in	1 year.		
	÷						
PUBLICATIONS OR AB	STRACTS, FY-8	32: NONE					
Study Objecti	ve. conf	inued: va	arious	studí	es with	res	nonse fre

Study Objective, continued: various studies with response frequency and remission duration in order to indentify subgrous of ALL.

Technical Approach, continued: fication, maintenance, and prophylactic CNS rx regime A = 6 mp 200 mg/m2/d x 5 Mtx, 7.5 mg/m2/d x 5, regimen B = DNR 45 mgm/m2/IV x 3, AR C 100 mgm/m2 x 7.

15:1: 10-2-82 Max Car N	h.: 1587	Status	: Interior X	Fire
START ING CARE: 10-80				
her loses: Chemotherapy-				
Titus sa froudut: CALGB # 8	3082 - Surgical A	Adjuvant C	hemotherapy o	f Stage II
Breast Carcinoma.				
Foundial Houseterator(s):	Raymond B. Weiss	s. M.D.		
AUSOCIATE INVESTIGATOR(S):				
FACILITY: 124°C	Papr/Sig: Her	matalogy/0	ncology - Dep	t. Of Med.
AccumuLarive MEDCASE Cost:	ACCUMULATIVE CONTR	ACT COST:	Acceptation in Se	IPPLY COST:
	<u> </u>		0	
F7-00 PELCYSE: Confract Con	17: SINLY COST:	BAGE OF PARTICL	Countries Weron Chouness Report	/AL 0# FEB 2.5 1983
Signable 2. 1: to compare Adriumycin in treatment of and estrogen receptor stored Reg 1: Reg 2: 0 Francis Sanda FY 52: To date still without evidence	CMFUP monthly AMFUP q 6 weeks Amfup q 6 weeks Amfup q 1 weeks	/ / with or	without later	Adriamycin
Humsen in Susurons Sido, Au: FY-SC: 13 Total	(TO DATE): 17	BEFO	RE COMPLETION OF	STUDY: CALGE -30
Sanious/Unappected Subs Effect NONE	s in Subjects Partic	PATHIS IN P	ROUECT(IF NONE SO	STATE):
Conclusions.	and actively a	ccuring pa	itients. Too s	toon to formula

10-2-82 1588 X 1-81 6-84 Localized small cell carcinoma of the lung. CALGB # 8083 - Localized Small Cell Carcinoma Of The Lung. A Phase II Study. Simultaneous Chemotherapy and Radiotherapy VS. Sequential Therapy (Chemotherapy, Radiotherapy, Chemotherapy) VS. Chemotherapy Alone. Raymond B. Weiss, M.D . Hematalogy/Oncology- Dept. Of Med. .. To test whether chemotherapy and radiation to primary tumor and mediastinum is superior to chemotherapy alone in patients with limited small cell lung cancer. ... Regimen 1: Vincristine 1.4mg/m2/IV -Cytoxan 100mg/m2 IV -VP -16 80mg/m2 - Radiation RX to Primary Tumor +CNS To date only 8 patients have been entered. 3 are in complete remission. 3 are in partial remission, and 2 have refused further therapy, and have been taken off protocol. 3 0 0 0 0 8 75

NONE

WRAMC experience indicates good rates of remission with above listed

Severe Myelosuppression with chemotherapy following radiotherapy.

therapy. Toxicity from this can however, be prohibitive.

DATE: 10/2/82	ож бил По.:	1589	STATUS: INTERIM	Final_x
STARTING DATE: 11	L-8 <u>0</u>	DATE OF	CONSTRUCT: 10/82	
Key 10003: Cisplat	in in patie			
T			patients with Gas	tric Cancer.
PRINCIPAL INVESTIGATE	oa(s): Ra	ymond B. Weiss,	M.D.	
ASSOCIATE INVESTIGAT	os(s):	·		· · · · · · · · · · · · · · · · · · ·
FACILITY: WRANC		DEPT/Syc: Hemato	logy/ Oncology- De	pt.Of Med.
ACCUMULATIVE MEDICASE	Cost: Acc	UMULATIVE CONTRACT (}	SUPPLY COST:
FY-83 PEDCASE: Con		Supply Cost:	DATE OF COMMITTEE PAPER FINNUAL PROGRESS REPORT	FEB 2.5 1983
Study Osjective: St unsesectable or m	udy anti-tu etastatic G	mor activity of astric Adenocar	single agent thera	apy in advanced
TECHNICAL APPROACH:	CIS _ PLATI	NUM 75mg/m2/IV	g 3 weeks	
PROGRESS DURING FY-82 while study was report.	Protocol active. pt.	closed 1982. On expired 3 month	nly one patient had ns later. This is a	l been entered a finalized
Mumber of Subjects St	נחסובס:			
FY-82: 0	TOTAL (TO	DATE): 1	Before Completion of	: Stuby: closed
SERIOUS/UNEXPECTED SI	IDE EFFECTS IN	SUBJECTS PARTICIPATI	ING IN PROJECT(IF NONE S	SO STATE):
	ant nausea a	and vomiting.		
CONCLUSTOMS:				
	NONE			
PUBLICATIONS OR ABSTR	ACTS. FY-82:			

DATE: 10/2/82 Mosk User M	D.: 1591	STATUS: INTERIM X	<u>Fire.</u>
STARTING DATE: 4/81	DATE OF	COMPLETION:	
KEY Nous: Refactory Adult	Acute Lymphoblast	ic Leukemia	
TITLE CF PROJECT: CALGB:# 8 Leukemia with Vincristi Cytosine arabinoside/6-	ne , Prednisone pl	Refractory Adult L us Tandem L-Asparag	ymphoblastic inase/ Methotrexate and
PRINCIPAL INVESTIGATOR(S):	Ravmond. B. Weiss	. M.D.	
ASSOCIATE INVESTIGATOR(S):			
FACILITY: KRAYE	DEPT/Svc: Hemate	ology/ Oncology- De	pt.Of Med.
ACCUMULATIVE MEDCASE COST:	ACCUMULATIVE CONTRACT	Cost: Accumentes S	UPPLY COST:
00			
FY-83 FEDCASE: CONTRACT COST	00	DATE OF COMMITTEE APPROACH	VAL 0F FEB 2.5 1993
STUDY OSJECTIVE: To establ who are in repaspe. To	ish probable remis		
TECHNICAL APPROACH: Induction paintance = Methotrexat	n = Vincristine, P e and L- Asparagin	rednisone, MTX adn ase.	L-Asparaginase at ml:
PROGRESS DURING FY-82: No	patients entered d	uring 81 - 1 patie	nt entered 82
NUMBER OF SUBJECTS STUDIED:			
FY-82: 1 TOTAL	(TO DATE): 1	BEFORE COMPLETION OF	Sтиру: 75
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	IN SUBJECTS PARTICIPAT	ing in Project(if None s	O STATE):
CONCLUSIONS: To early for 4-5 patient per year in	conclusion on 1 pa this very promising	atient entered. We age Modality.	expect to enter
Publications or Abstracts, FY-8	2:	 -	
NO	NE		

DATE: 10/2/82 Now UNIT !	o.: 1592	STATUS: INTERIM	Free X
STARTING DATE: 4/81	Dare of	COMPLETION: 12/8	1
KEY MORDS: Advanced unre	sectable recurrent	Renal Cell Can	cer.
TITLE OF PROJECT: CALGB: 81 recurrent Renal cell Ca	72: A phase II stud	y for advanced ermanium .	unresectable or
PRINCIPAL INVESTIGATOR(S): R	aymond B. Weiss, M.	D	
ASSOCIATE INVESTIGATOR(S):			
FACILITY: HRAYC	DEPT/Svc: Hemato	logy/Oncology-	Dept.Of Med.
Accumulative MEDCASE Cost:	Accumulative Contract C	<u> </u>	TIVE SUPPLY COST:
FY-83 PEDCASE: CONTRACT COS		DATE OF COMMITTEE FUNDAL PROGRESS RE	FEB 2.5 1980
STUDY OBJECTIVE: Evaluate an unresectable or metastate TECHNICAL APPROACH: Sporoger 80 mg/m2/ Iv 2x weeks	tic ademocarcinoma o ramium 80mg/m2/ IV g	of Kidney . good for 3 dose	esx 2 weeks, the
ROSRESS DURING FY-82: WRAMC Protocol is now chosed			
Number of Subjects Studied:			
	(TO DATE):		ON OF STUDY:Closed
SERIOUS/UNEXPECTED SIDE EFFECTS None	S III SUBJECTS PARTICIPATI	ns in Project(if i	ONE SO STATE):
Conclusions: No data act	rued, therefore no	conclusions.	
PUBLICATIONS OR ABSTRACTS. FY-8	Ω:		
NONE			

DATE: 10/2/82 Hosk Unit N	0.: 1593	STATUS: INTERIM X FIRM
STARTING DATE: 6/81	DATE OF	COMPLETION:
KEY MORDS: Recurrent Mets	static Breast Carcin	noma
TITLE OF PROJECT: CALGB:81 treatment of Recurrent/Motherpay.		rial of Aclacinomycin -A in the cer Refractory ot Conventional
PRINCIPAL INVESTIGATOR(S): R	aymond B. Weiss, M.J	D
ASSOCIATE INVESTIGATOR(S):		
FACILITY: MRAYE	DEPT/Syc: Hemato	logy/Oncology - Dept. Of Med.
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT C	COST: ACCUMULATIVE SUPPLY COST:
FY-83 I'ERGISE: CONTRACT COS	T: Supply Cost:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 25 1945
failing conventional the	rapy. ing on performance s	of single agent therapy in nt carcimoma of the Breast score and extent of prior treates 3 weeks.
All had progressive dise disease.	te only 3 patients ase, 1 has expired.	have been entered on this study. the remaining 2 are alive with
Number of Subsects Studies:		
FY-82: 0 TOTAL	(TO DATE): 3	BEFORE COMPLETION OF STUDY: 75
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPATI	HS IN PROJECT(IF HOME SO STATE):
Transient EKG abnorm	alities, Phlebitis.	
CONCLUSIONS: Data too spa	rse to make any con	clusions.
PUBLICATIONS OR ABSTRACTS, FY-	82:	

					
DATE: 10-2-82	HORK UNIT NO. :	1594	Status	! INTERIM	Firm X
STARTING DATE: 4-	-81	<u>D</u> ;	TE OF COMPLET	ion: 6-82	
KEY HORDS: AZO	in patients	with previou	sly treate	d Myeloma	
					s with previousl
treated Myelo				·	
PRINCIPAL INVESTIG	eator(s): R	aymond B. Wei	ss, M.D.		
ASSOCIATE INVESTIG	EATOR(s):				
FACILITY: WRANC		DEPT/SVC:	Hematology	/ Oncology	- Dept. Of Med.
Accumulative MEDCA	SE Cost: /	ACCUMULATIVE COM	RACT COST:		SUPPLY COST:
OO FY-83 NEDCASE:	CONTRACT COST:	S:130: V (05T:	Date of	COMMITTEE REP	POVAL DE
	09	00	FARUAL	PROGRESS REPOR	FEB 2 5 1983
STUDY OBJECTIVE: patients with TECHNICAL APPROACH day 14: AZQ 35 PROGRESS DURING FY This is a fina	Multiple Mydi: AZQ 30-mg. Smg/m2/IV.	eloma. /m2/IV g 3 we ient were eve	eks, if no	immunosupp	
Number of Subjects	: ביוסטדבי				
FY-82: 0	TOTAL (1	TO DATE):	O BEFO	RE COMPLETION	OF STUDY:Closed
SERIOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PARTI	CIPATING IN P	ROUECT(IF HONE	SO STATE):
none		· · · · · · · · · · · · · · · · · · ·			
CONCLUSIONS:					
None	e				
PUBLICATIONS OR AS	STRACTS, FY-82	;			

DATE: 10/2/82 NOSK UNIT NO	.: 1595	STATUS: INTERIM X FIRM
STARTING DATE: 6/81	DATE OF	COMPLETION:
KEY KORDS: ADC in patient	s with advanced or	recurrent Colon or Rectal Cancer
TITLE OF PROJECT: CALGB:# 81 with advanced or Recurren		arboxaldehyde (ADC) in patients Cancer.
PRINCIPAL INVESTIGATOR(S): Ray	mond B.Weiss, N.D	<u> </u>
ASSOCIATE INVESTIGATOR(S):		
FACILITY: NRAYC	DEPT/Syc: Hemato	logy- Oncology -Dept.Of Med.
ACCUMULATIVE MEDCASE COST: 00	ACCUMULATIVE CONTRACT CO	OST: ACCUMULATIVE SUPPLY COST: OQ
FY-83 PEDCASE: CONTRACT COST:	: Supply Cost:	DATE OF COMMITTES PARROVAL OF PANNUAL PROGRESS REPORT FEB 2.5 1983
able or metastatic Adenoc	m/m2/IV g 3 weeks.	erapy in advanced non- resect- an Rectum. If no immunosuppression on
PROGRESS BURING FY-82: this p	rotocol was closed e 6 have expired.1	11/81. 6 patients have been of the 6 is alive with disease
FY-82: 0 TOTAL ((TO DATE): 6	BEFORE COMPLETION OF STUDY: closed
NONE		IG IN PROJECT(IF NOME SO STATE):
Conclusions ADC has shown li Colorectal Cance		cy in patients with advanced
Publications or Abstracts, FY-82	: :	

						=
DATE: 10-2-82	Mask Unit No.:	1596	STATUS	INTERIM X	Fine	
STARTING DATE: 2	? -8 1	DATE OF	COMPLET	ion: 6-85		•
TITLE OF PROJECT:	CALGB + 8084	noma of Lung Small cell card	cinoma		extensive di	Isease a com
ison of MACC plu	ıs warfarin t	o MEPA alternat:	ing wit	h MACC.		
						-
PRINCIPAL INVESTIG	CAroa(s): Ra	ymond B. Weiss,	M.D.			-
ASSOCIATE INVESTIG	SATOR(S):					-
FACILITY: HRANC		DEPT/Svc: Hemai	tology	/ Onclolgy ,	Dept. OF Me	ed.
ACCUMULATIVE PEOC	ASE Cost: A	CCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE	SUPPLY COST:	-
00		00		00		-
	CONTRACT COST:	Supply Cost:	Date of Finnual	COMMITTEE FARR PROGRESS REPORT	OVAL OF	· -
trol. Determine Luate nuerophyci TECHNICAL APPROACE Adriamycin 40mg Infarin sodium. PROSRESS DURING F	if alternatin levels before MACC vs. /m2/IV, Cyto. Reg: 3 Mitom (-82: To date remaining 3	ther addition of ing combination Nore, during, ar MACC +warfarin wan 400mg/m2/IV, ycin-C /mg/m2/IV only 9 patients patients are in	IEPH/MA Id afte Vs. MEP CCNU Cis have l	CC will prolor chemotheraph H+MACC; reg 1 30mg/m2/PO. Folatin 50mg/m been entered.	ong disease L: Methetre Reg 2: same 12/IV, VP-16 Of these 9	control. xate 30mg/m2 as regimen 1 40mg/m2/IV patients,
FY-82 <u>: 3</u>	TOTAL (T	O DATE): 9	Befo	RE COMPLETION O	F STUDY <u>: 75</u>	-
Sarious/Unexpected NONE	Side Effects 1	N SUBJECTS PARTICIPA	ring in F	NOUSECT(IF HONE	SO STATE):	-
CONCLUSIONS: WRA	MC experience listed che	e is about 33% s mo. regimens.	uccess	in acheiving	good remis	- sion
PUBLICATIONS OR AS	STRACTS, FY-82:					_
NONE						

DATE: 10/2/82 NOSK UNIT N	o.: 1597	STATUS	S: INTERIM	Final X
STARTING DATE: 5/81	DATE	OF COMPLET	rien: 12/8:	1
KEY NORDS: AZQ_tre	eatment of Acute	Myelocyt	ic Leukemia	
TITLE OF PROJECT: CALGE # 8		-		
patients with refactory A	Acute Myelocytic	Leukemia	in adults.	
PRINCIPAL INVESTIGATOR(S): F	Raymond B. Weiss	, M.D.		
ASSOCIATE INVESTIGATOR(S):				
FACILITY: MRAYC	Dapt/Syc: Hema	atology /	Oncology -	Dept. Of Med.
ACCUMULATIVE MEDCASE COST:	ACCUMULATIVE CONTRA	CT Cost:	ACCUMULATIVE	SUPPLY COST:
00	00	·	00	
FY-83 FEDCASE: CONTRACT COST	T: Supply Cost:	DATE OF FAMUAL	F COMMITTEE APP. PROGRESS REPOR	ROVAL OF F FEB 2.5 1983
STUDY OSJECTIVE: Eval-uate chemotherapy in treatme				agent or combinati
	mg/m2/dx7 as ind mg/m2/dx5 as mai			
PROSRESS DURING FY-82: No pa This protocol was closed	itients were even			
HUMBER OF SUBJECTS STUDIED:				
FY-82: 0 TOTAL	(TO DATE): 0	Befo	ORE COMPLETION	OF STUDY: closed
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	s in Subjects Partici	PATING IN P	ENCH 11) TOELON	SO STATE):
CONCLUSIONS: No conclusion	onsas no data was	gathere	d .	
,				
PUBLICATIONS OR ABSTRACTS, FY-8	32:			
• • • • • • • • • • • • • • • • • • • •				

NOne

10-2-82		
_Copyrigue_Copyrigue_3_		
DHAD		
Liver Cancer.	CALGB# 8178 -DHAD	- In Batients with Advanced Primary
	/ : Paymond P	Motor M.D.
1465 (20.1262) An am bankata	Raymond B.	weisa, M.D.
		Hematology/Opeology -Dont Of Mod
		Hematology/Oncology -Dept. Of Med.
		nude Charles & Filters Abbus a mouse Dominis (1999) O
0	14.73	0 Q FEB 2.5 1983
or metastatic p	To determine effic rimary liver cance	cacy of DHAD in patients with resectable er.
Tigeport Lecover	DHAD 12mg/m2 IV	q 3 weeks.
response . Is a	1 patient ente	ered. Had 2 cycles of drug and showed no sive disease.
Numera on Subutors (ਜੁਕਾਵਾ:	
FY-82: 1	Total (to pairly	1 Barone Commercial of Shoppy 20
SI 10000 AND PROTED IN NO.	Side Eevects in Subject NE	Ta Mustic Hot models Reported Commons and analy)
C. AMELOR: NONE		
Test 12/1/20 12 /USI	record. I Y-C-1	

Archives Int. Med. Oct. 82 (in press) Michael Hurwitz, M.D. M.C.

10-2-82	J	1599			$ar{\mathbf{X}} = \mathbf{Y} \cdot ar{\mathbf{Y}}$
1 1 2-1	32		e-	2-	83
Refracto	ory Hodgkins	s Disease			
CAI	• • • • • • • •	** *		ctory Hodg	kins Disease
Resistance to Star				,0	
omen and an experience of the second of					
La trancia esta ana	Raymo	nd B. Wei	ss. M.D.		
Augustate Reventions	•				
FACILITY: 17/17		1 pp r/S -	Hematalogy/	Oncology -	Dept. Of Med.
Focustalative (2004)					
0 PY-83 MECASE: Co.	TRACT COSTS	<u></u>	1 0.00	or Colorer	Intracuri, Cr
0	0	0	المراه و ا	_ Fall ress he	PORT FEB 2 5 198
Hexamethylmelaming Repeated q 21 days therapy.	e 100mg/m2 s	po day 2-	8 and Predn	isone 32mg	/m2 po day 2-8.
Harry 1 Sustains 3	98.23;				
FY-20: 1	Toral (ru	(2)(5) <u>:</u>	1 F.	FELE COMMISS	20 pt Single 20
Substitute of Pechet S. NONE	DE CEPECTO LI	S buscas fa	TIC post time to	Partier,	WE SU STATED.
Carona a Data	too sparse	to formul	ate any con	clusions.	
	•				
PUBLICATIONS OF ABST?	ACTS. Piroli				

10-2-82	1500-82 X 21-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4
_C	The Appendix
ARA-C L. Asparig	inase ,Acute Myelocytic Leukemia
Given Sequentially With L-Aspa	Comparative Study Of High Dose ARA-C Alone or raginase for Remission Induction in Patients With pe.
Provide Residential Raymond	B. Weiss, M.D.
Amore Thereses Hill	
Control WW.	Hematalogy/Oncology -Dept. Of Med.
Accordance Transport Course Accord	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
ren 1861 - Grangon o Si	0-4 St. Ft. Feb. 2.5 1983
	and the second of the second o
To determine eff	icacy of high dose ARA-C with our without
and the same of th	nduction in patients with AML refractory to
The last line the	erapy.[
Reg 1: ARA-C 3gm/m2 IV + L-As; Reg 2: ARA-C 3gm/m2 IV.	p. 6000 IV /M2 IM
3 of the patients never achieve	eviously treated AML patients have been entered ed remission and have since expired. 2 of the Pt's
There is to be stored from the first terms of the store o	alive and still being treated according to Protocol/ relasped but is alive.[
FY-00, 6 Total (p) to:	1): 6 Romaile Commencial of Shoppi CALGB-200
Capitous (Signature) Signatures of Signature	CICED PARTICIPATION IN POR COPERA NONE BUILDING
NONE	
<u>C. 222</u> (4)	
Data too sparse to i	formulate any conclusions. Low patient
Tourismus Despession (St.	
NONE	

Page 10-2-82 May 1 at 1					
Statistic Perc: 2-82	[3]	a free co	11.09	-82	
New November ADC - Carcinoma Time of Passisti CALGB #816 Im Advanced Carcinoma of	, Lung 41 - Phase II tria	al Anth	racenadic		
Frinciphi, Imasticatoulali	Raymond B. Weiss	, M.D.			
ASSOCIATE LIWESTICATOR(S):					
FACILITY: MAYO	Dspr/Svc: Hemat	ology/	Oncology_	- Dept. Of Med.	
ACCUMPLATIVE PEBCASE COST:					
			<u> </u>	0	
FY-85 1000ASE: Contract Cost	7: Stove / Cost:	BATE OF LANGAL	Cow.ntcs Prosness Res	ieorowy be rori FEB 2.5 1992.	
Study Coulcins: To determine metastatic lung cancer of Transportation ADC 260m Prostess During 17:82: 6 patricises and have expired, 1 pt. has progressive, by Hussia of Susuncia Studied: FY-62: 6 Journal	mg/m2 IV q 21 days ients have been en	ell.	oo date. X1 pt. st put on	2 pts. had prog has stable dis study 9/92.	ressive ease
Strious/Unexpected Sine Lesect: Phlebitis in vessell	l where IV Drug wa	s infus	ed.		
Concentions: Data too sparse Fuscications on Assigners, FY-8 NONE	e for conclusion a	t this	time.		

Tare: 10-2-82 Wast	Sacr (15. : 1	1502-82	Status	i literaly X Fire	<u> </u>
Stations Pare: 9-81		IME O	E COMMET	10:1: 9-83	
Lev Louis Advanced (Or Rocurre	nt Metastatio	lelano	ща	
Title of industry calor The Treatment Of Adv					tin in
Principal Investigators): Raymon	nd B. Weiss,M.	.D.		
Associate Divestigator(s): 				
FACILITY: NRAWC		Dapr/Svc: Hema	talogy/	Oncology -Dept.Of	Med.
Accumulative TEBCASE Cos	r: Accu	MULATIVE CONTRACT	Ce37:	ACCUMULATIVE SUPPLY	Cost:
PY-85 MEDDASE: CONTRAI	ct Cost: S	O UPPLY COST:	I Days	0	
_ '	L	0	PARE OF	COMMITTEE PAROVAL OF PROURESS REPORT FEB	2 5 1983
Stear Conceive: to est quencies in patients	ablish to with adv	lerability of anced Melanom	VDP, to a treat	o establish CR or ed with VDP.	Pr fre-
Cie	arbazine Distin 50	150mg/m2 TV d	ay 1-2-	and 3	
to therapy and progr treated every month.	patients essed. 2	have been ent of the 5 have	ered. 3	of the 5 had no magood PR and are st	esponse
Minister of Subuccis Studies	:o:				
FY-32: 5	TOTAL (TO P	47E): 5	BEFO	RE COMPLETION OF STUDY	60
Strious/Grewected Side E NONE	FFECTS IN S.	ισ υσότα Γλ αττοίρλ -	ring in P	ROUZOI (15 HONE SO STAY)	<u>=):</u>
Concentrations: NONE					
Faultications on Fastracts	. FY-S2:	•		,	
NONE					

CALGB# 8 for Patients with Smal	177 - Superfractio 1 Cell Carcinoma o 8083	nation Rafi the Lui	adiotherapy and Chmeotherapy ng Who Fail Locally after
•			
Ascionate Investmanca(s)	Lange of Hom	ntalogy/	Oncology - Dept. Of Med.
			/ COMPLATIVE SUPLY COST:
PY-85 PYEQUES Compact C	COST: SURPLY COST:	Direction	Colorgrand Advantage Ca Paulagean Rescur FEB 2 5 1987
0 0			1901
	mine the tolerabil	ity of S	uperfractionation Radiothers
STERY CONCINE: to determine patients with limit Transfer And Mar Radiat areas, 30 treatments is and Cytoxan.	mine the tolerabiled small cell carcion RX. to tumor, n 3 weeks (2 A day	ity of Soinoma of	uperfractionation Radiothers
On patients with limit reas, 30 treatments in determined Cytoxan. NONE	mine the tolerabiled small cell carcion RX. to tumor, n 3 weeks (2 A day	ity of Soinoma of	uperfractionation Radiothers the lung. num, and supraclavicular
Stray Concerns: to determine patients with limit areas, 30 treatments is and Cytoxan. NONE	mine the tolerabiled small cell carcion RX. to tumor, n 3 weeks (2 A day	ity of Sinoma of Mediastin) chemoth	uperfractionation Radiothers the lung. num, and supraclavicular
STLLY CONCINE: to determine patients with limit areas, 30 treatments is and Cytoxan. NONE NONE	mine the toleratiled small cell carcion RX. to tumor, n 3 weeks (2 A day	ity of Sinoma of Mediastin) chemoth	uperfractionation Radiothers the lung. num, and supraclavicular nerapy of MTX, Adria, CCNU,
Stury Concerns: to determ on patients with limit rates, 30 treatments in and Cytoxan. NONE NONE NONE	mine the toleratiled small cell carcion RX. to tumor, n 3 weeks (2 A day	ity of Sinoma of Mediastin) chemoth	uperfractionation Radiothers the lung. num, and supraclavicular nerapy of MTX, Adria, CCNU,

10-2-82 1504-82 X
2-83
Bisantrene - Breast Cancer
CALGB # 8142- Phase II Trial of Anthracenedicarboxaldehyde
for Advanced Breast Cancer .
Francow issassass' Dr Raymond B. Weiss, M.D.
Pustonate Indestigaton(SI):
FACILITY: ARANG IEST/Syc: Hematology/Oncology - Dept.Of Med.
- Income struct PENIASS Footh - 1 France attive Contract Cost: 1 Figure 1975 Line Microsoft
0 0 0 0 0 FIGURE CONTRACT COT: \$ 2017 COUT. District Court of Co
Strips: to evaluate efficacy of ADC for significant anti-tumor activity in the treatment of inoperable, advanced or recurrent carcinoma of the breast. ADC 260mg/m2 IV q 21 days.
So far only 2 patients have been entered . 1 had progression after 2 doses. the other has only been on study 1 month.
Finance Suburbus Suburbus
FY-80: 2 Total (miles). 2 Rusake Inselection of St. or. 20
Stric 207 Bisparento Sing Effects in Structs Factors, this to Panateticn pane in Structure NONE
Data too sparsefor formulation of any conclusions.
Purelications of Assistances, FY-62:

10-2-82	1506-82		X	
8-82	• • • • • • • • • • • • • • • • • • •	, 1	8–85	
	sease -MOPP, ABVD	=+-		
ized Phase III Trial Con	251 - Treatment Of	Advanced IN VS MOR	l Hodgkins Disea PP Alternating w	ise: A Random-
ized Phase III Irlai Con	mparing norr vs and			
	Raymond R. Weiss	M.D.		
of material field to the Association				
		talogy /	Oncology -Dept.	Of Med.
Action Apple 1200/13 Coor:	I fotor wines Contrac	.f (bif:	Floor in Wine Guer	LY Coom:
0 7/46) 14/6/14: Caparis C		1.00°E	Or wysten Awerung No Geess Repout FEB	2 5 1983
5 20 Comparing: To compar patients with stage III	e efficacy and tox	icity of	3 treatment rep	
Regimen III - MOPP ever	1: MOPP every 28 ry 28 days alternat	ing with	egimen 2: ABVD of ABVD the next	every 28 days. 28 days.
Fried Care W. 12: To c			een entered.	
Makelik on Suscrom Subdulat	an tan ng magatini mang na 1864 i Ni matatapa ng matatapa na matatapa ng matatapa na matatapa na matatapa na m			
FY-12: 3 Tor	:L (10 DAVE): 3	Paro	we Community on CF St	WRAMC 12
Suproved Ventagrad Orda Lave NONE	ots in Julysta Skritch	s fill. In F	ina dattan uma 2003 -	mati):
None at this interpretation.	time. Too early f	or data	accumulation an	d
	Y-62			

DATE: 10-2-8	2 HORK UNIT A	io.: 1627	STATU	S: INTERIM X FIRE	_
STARTING DATE	: 1974	PATE	OF COMPLET	Clsoed 2/16/78	
KEY VORJS:	Carcinoma of	Lung.			
TITLE CF PROJ of patients with			c-1 eva	luation and immunotherap	
PRINCIPAL IN	ESTIGATOR(S):	Raymond B. Weiss	M.D.		_
ASSOCIATE INV	ESTIGATOR(S):				 -
FACILITY: W.	4NC	DEPT/Syc: Hema	tology/	Oncology , Dept. Of Med	<u>i.</u>
Accumulative i	ENCASE Cost:	ACCUMULATIVE CONTRAC	г Созт:	ACCUMULATIVE SUPPLY COST: 00	-
FY-83 PEDCAS	E: CONTRACT COS		DATE OF ANNUAL	COMMITTEE APPROVAL OF PROGRESS REPORT FEB 2 5 198	- <u>-</u>
tion of in vi TECHNICAL APPR BCG of follow-u rads plus rando PROSRESS DURIN	vo and invity ROACH: Stage 1 p alone. Stage mization vs. 46 FY-82: [IV +	co cellular immun (A) patients were se ll-debulked sur above. they also Vincristine 2.0mg	ity with rendomi gically received IV day	of BCG given by scareficenic tumor cells benefit a clinical status. Ized hetween BCG, tumor received raceived radio a cytoxan 500mg/m2 Method 1-8 -928D.	cells and otherapy 5000 otrexate 40mg/
Protocol close are either off	d since 2/79. study due to	All stage B pati the logistics of	ents har following	ve expired. The stage Ang them off post or are	patients (7) lost to follo
HUMBER OF SUB.	iscre Studied.	one glosed			together
FY-82: 0	TOTAL	(TO DATE): 21	Вего	RE COMPLETION OF STUDY:	
SERTOUS/UNEXPE	CTED SIDE EFFECT	S IN SUBJECTS PARTICIPA	arins in P	ROJECT(IF NOWE SO STATE):	
no ser	ious /unexpec	ted side effects			
Conclusions: periods of	Immunotherapy remission in	appears to be of patients with lu	minima ng cance	l value in prolonging l	ife span
PUBLICATIONS O	R ABSTRACTS, FY-8	52:			-

DATE 10/2/82	HORK BUIT NO	.: 1628	STATUS	S: INTERIM	Froe X			
STARTILE DATE:	DATE: 1976 DATE OF COMPLETION: 10/82							
Key Words: Carcinoma of the Large Bowel								
TITLE OF PROJECT:	WRAMC:# 74	06 - Chemoimmunot Bowel	herapy	of Carcinoma	of the Large			
PRINCIPAL INVESTIG		aymond B. Weiss,	M.D.					
ASSOCIATE INVESTIG	GATOR(S):							
FACILITY: HRANC		DEPT/Svc: Hemat	ology/	Oncology - De	ept.Of Med.			
Accumulative MEDC	ASE Cost:	ACCUPILATIVE CONTRACT	Cost:	AccumuLative S	SUPPLY COST:			
FY-83 i EDCASE:	CONTRACT COST	: Supply Cost:	DATE OF ANNUAL	COMMITTEE APPROPRIES REPORT	FEB 2 5 198			
STUDY OSJECTIVE: To investigate the therapeutic officacy of BCG by dermal scarfication in patients with carcinoma of the Colon or Rectum when combined with 5-FU combination with 5-FU/ MECCNU. TECHNICAL APPROACH: All patients are classified according to Duke's C classification: Type II (Stage B) - extension into but not through muscularis. (STage B2) - extentsion to or through serosa; negative nodes. III (Stage Cl-below Problems Purious FY-82: This study closed to patient entry May 1978. Total of 20 patients entered to date all have expired or are lost to follow-up.								
Muraea or Suauecis		. 20		_	Closed			
FY-82: 0	IOTAL ((TO DATE): 20	Befo	RE COMMETION OF	STUDY: CLOSED			
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE): NONE								
Co musicas: Will be analyzed for publication in 1983. 5 year survival information.								
Publications of As	STRACTS FY-82	2:						

Technical Approach, continued: limited to serosa; positive nodes. IV - Locally metastatic disease beyond lymphatics, the bulk of which can be removed, but with some tumor remaining, cannot tolerate surgery. Tumor of such size, or fixed so that surgery would not be undertaken, V (stage D) distance metastataeses.

10-2-82	1630	Tapaper		, X
1974	in.	· (5-4-5)	9-81	
Tamoxifen, Fluor	xymesterone, Meta	static B	reast Cance	r
Fluoxymesterone plus Tam	7408 - Comparative	e trial (of Tamoxifa	
<u> </u>	aymond B. Weiss,M	.D		
Francisty: 184%	Dept/Syc: Hem	atalogy	Oncology -	Dept.OF Med.
0	Accuration (ve. Contract O		0	
FY-65 MEDIAGE: Commant Cos	57: Seprez (587:	DATE OF LAURE	Countries Apr Lacoresis Repo	FEB 2.5 1983
Story 13. 20174: Response relative therapeutic ber The CAL France: Regimen Regimen	A: Tamo ifen 2mg B: Fluoxymesteron	regimens g/m2/ po ne 7 mg/m	bid.	
entered 4 are lost to for progressed.	has been closed of	this year t evaluat	of the paidle, and al	atients previous the others hav
Harber of Courses Stephen				
F1-82: 0 Total	(10 pars): 40	EFF	ME COMMETION	07 Study:_20
Junior Will Extention Stoe Settlin	क १७ विषयम् । स्थापन	William !	1307(11)30	10 STATE 1
NONE				
Pending complete	tion of reyiew,			
Transfer (Stransfer FY-	.:.			** - * ** ** ** ** ** ** ** ** ** ** **

Para: 10-2-82 Now Lear !	1649	i ijyarus	interior	X	(1) Pr.
Smara fare: 1976		CWHIT	ion: 19	31	
Ver Neus: Prostatic Chem					
Title of Fracest WRAMC # 76	002 - Chemiommuna	therapy o	f Prosta	tic Carc	inoma
Frincipal Transferratorios (1).	Raymond B. Weiss	.M.D.			
ASSOCIATE INVESTIGATOR(0):					
FACILITY: 18470	DEPT/Syg: Hem	atalogy/C	n-cology	- Dept.	Of Med.
Accumulative MESCASE Cost:	ACCUMULATIVE CONTRA	or Coar:	/.ccunut.at	IVE SUPPLY	
0	<u> </u>		0		
FY-33 PELCOSE: Centract Cot		DATE OF	Committee Paparess Re	ierzoval (i Port FF	E 2.5 1983
Study 03.4.Cli.5: to study t and 5- ? Flourouacil wit of advanced Stage D Card	the efficacy of the and without_BC	he combin G immunot	ation of herapy in	Cyclophe the tre	osphamide eatment
of advanced Stage D Card	inoma of the Pro	state.			
600 mg/m2 IV on days 1 a	A: Cyclophospham and 8: BCC 6x107	ide 1000 8 units o	mg/mys ¹ 1	A Bana li	5-Flourouracil Regimen B-
Cyclophosphamide 1000 mg					
did not complete evaluat	tion prior to dep	arting se	rvice in	FY 81.	(00000)
Naiser of Superors Studies:		 -			
FY-82: 0 Total	(TO DATE): 20	Вароз	RE COMPLETI	פטו כ דים ויס	_{:v:} 20
Somious/Chempeoted Side Eafect					
NONE	5 10 03302015 (ME [U])	Sale da de la Caraca de Caraca Caraca de Caraca de Carac	(DOZOTE) F.	ORE 50 STA	(TE);
Conclusions Pending complete	tion of review				-
- G	OI ICVICA				
FUELICACIONS OR ASSIRACTO, FY-8					

Technical Approach, (continued): this cycle to be repeated every 28 days. Addendum #1 changed the BCG vaccine to the Pasteur strain, 2 - 8 x 10/8 viable units.

DATE: 10-2-82 Mark true II	1658	Artier dager	X :
Saarma (1988) 1977	(1984	The state of the s
NEW Horosa Prostate Card			
Title of Medica: WRAMC # 77			tate Carcinoma
with Adriamycin and Cis-	-Diamminedichoropiat	inum II.	The second secon
Principal (MASTIBATOR()): Ra	ymond B. Weiss, M.D	•	
ASUCCIATE INVESTIGATOR(S):			Manager and the state of the st
Fictury: 1840	Papt/Syc: Hemata	logy /Oncology -	Dept. Of Med.
0	ACCUMULATIVE CONTRACT C	DET: POCULUS ITAVE Q	: Suenth Cost:
FY-83 MACCAGE: Confraact Cost	T: Supply Cost:	PALE OF COUNTRIES APP WHUAU PRUTESS REPOR	PROVE 02 FEB 2 5 1983
Figure 5 Subjects Studies:	theapy plus chemot and histologically A- Whole pelvic irac rads to the prostate IV day 1 every 28 patients entered for tients entered provers (TO DATE): 2	herapy in the troproven stage D1 adiation to a to e bed. Regimen B days.Cis-Platinu FY 81. iously. Before Completion	eatment of patients Prostatic Carcinoma. tal dose of 4600 -rads. : Radiation therapy as m 60 mg/m2IV day 1- belo
NONE			e manimus de como es con esta conferencia de constante de
Clsoe study b	ecause of poor pati	ents accural.	
FUNCTONATIONS OF FRANCIS, FY-8	<i>(4)</i>		
NONE			
Technical Approach: type of patients eligadministration of CIS	gible for this pr	otocol. Adde	ndum #2 modified

DATE: 10/2/82 Nox Uvit Ho	0.: 1665	SIATUS	INTERIM	Fire X	
STARTING DATE: 1977	DATE OF	COMPLET	ion: 10/82		
Key Nords: Gastrointest	intestinal Tumors				
TITLE OF PROJECT: WRANC: # 77	706 - Treatment of	Refrac	tory Gastroin	itestinal	
tumors with Chlorambucil	and Methotrexate.	·			
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss,	M.D.			
ASSOCIATE INVESTIGATOR(S):			ov. 1 D	OF MED	
FACILITY: NRANC	NEPT/Syc: Hemat				
ACCUMULATIVE NEBCASE COST:	ACCUMULATIVE CONTRACT 00	Cost:	ACCUMULATIVE S	SUPPLY COST:	
FY-83 FEDCASE: CONTRACT Cost 00 00	T: SUPPLY COST:	DATE OF EMMUAL	Committee APPRO Procress Report	DVAL 0= FEB 2.5 1983	}
STUDY OBJECTIVE: To test the Methotrexate in patients TECHNICAL APPROACH: Chloroad 1-4-8-12 (po) this course prior chemotherapy or range of the course prior chemotherapy or range of the chemotherapy of the PROSRESS DURING FY-82 WRAMC past year. We can obtain as they are either dead of the chemotherapy of Total Serious/Unexpected Side Effect	with advanced Gas mbucil 6.0 mg/m2 de is repeated ever diotherapy, 75% of has entered no pa no further inform or lost to follow— This is a finalize (TO DATE): 19	ays 1-1 y 28 d the do tients ation c up. Stu d repor	4 -Methotrex. ays. For pat sage is give on this study on previously ady was close tt.[ate 10mg/m2 ients who han for the fi y during the entered pat d 10/82.	rst cycle.
NONE					
CONCLUSIONS: NONE AT THIS PUBLICATIONS OR ABSTRACTS, FY-	TIME: STUDY IS CI	OSED.			-
NONE					

DATE: 10/2/82 Hask User II	0.: 1666	STATUS: INTERIM	Final X				
STARTING DATE: 1978 DATE OF COMPLETION: 10/81							
Key Mosos: Immunothers	apy						
Title of Project: WRAMC # and phase I of immunother	7801 - Protocol ferapy of patients	or immunologica ¹ (with various Carc	evaluation, inomas.				
PRINCIPAL INVESTIGATOR(S): R	aymond B. Weiss, M	.D.	· · · · · · · · · · · · · · · · · · ·				
ASSOCIATE TOVESTIGATOR(S):							
FACILITY: WANG	DEPT/Syc: Hema	tology / Oncology	-Dept. Of Med.				
Accumulative MEDCASE Cost: 00	Acquire at ive Contract	Cost: Accumulativ	E SUPPLY COST:				
FY-83 PEDCASE: CONTRACT COS		DATE OF COMMITTEE AP ANNUAL PROGRESS REPO	PROVAL 0= RT FEB 2 5 1983				
STUDY OSJECTIVE: To per m present and tumor entire TECHNICAL APPROACH: As per profoco	detailed immune enly resected, follow outlines submitted	wing immunization	, with C. Parvum -SEE				
Processes Dusting FY-82: Study portocol have expired. T	closed 10-81. At his is a finalized	this time ,all pa	tients placed on this				
Hunger of Subjects Studied:							
FY-82: 0 Total	(TO DATE): 7	BEFORE COMPLETION	OF STUDY: Closed				
Sarious/Unexpected Side Effect NONE	s in Subjects Participa	TIMS IN PROJECT(IF NON	E SO STATE):				
CONCLUSIONS: Data too sparse and patient follow-up too poor to formulate any conclusions protocol is closed and no further data will be forth coming.							
European Annual SV	00.		**************************************				
PUBLICATIONS OR ABSTRACTS, FY-82: NONE							
Study Objective: (changes in cytotoxidetermine if immune	continued) in	immune agents	, and to				

reversed.

DATE: 10-2-82	Mag. Lyer House	1667	\$14175	Literia	Farse X	
STARTING BATE:		DATE	C Comer	77: 10-81		
Key Mowas: Breas	st Carcinoma					-
Title of Paqueot: V	VRAMC # 7803	- Metastatio	Breast	Cancer		
						-
Principa livasite	Arck's' Raymo	nd B. Weiss, N	1.D.			
Associate livestic		· · · · · · · · · · · · · · · · · · ·				
FIGUREY: NOWL		Dept/Syc: Her	natalogy	/Oncology -	Dept. Of Me	d.
Footh, quarties PESQL						
<u> </u>	for to the Control	S. 254.31 - 24.74	L	00	f ·	•
FY-80 (ETL-61: 0		_0	ALAUAL F	HOLAS HEROLT	FEB 2 5 198	13
TECHNICAL ASSOCIATE From Fig. Lorenze FY North Ed. Co. Substants	Regimen 1: Regimen 2:	BCNU, Cytoxan, BCNU, Vincrist	, Vincris	hotrexate 		- ed•
FY-72: 0	lotal (to	DATE): 14	Befor	E COMPLETION OF	STUDY: 14	_
Stateos/dierofected NONE	Side Effects in	SUBUECTS PARTICIP	arms in Pr	CUBOTÉIF NOME S	SO STATE);	-
Compusitions: NONE						-
Fallatontims on /as	STAACTS. FY-S2:					-
NONE						

DATE: 10/2/82 Now Unit II	o.: 1671	SIATUS: INTERIA Y FIDE.
STARTING DATE: 1979	DATE OF	F COMPLETION:
Key Novas: Cancer of Colo	n	
		iplatelet Therapy for Duke's B2
or C Cancer of the Colon.		
PRINCIPAL INVESTIGATOR(S): Ray	mond B.Weiss, M.D.	•
ASSOCIATE INVESTIGATOR(s):		
FACILITY: MRAYC	DEPT/Syc:Hemato	ology/ Oncology -Dept.of Med.
ACCUMULATIVE MEDCASE COST:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:
00	00	00
FY-83 PEDCASE: Contract Cos	00	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 25 1983
STUDY OBJECTIVE: The aim of Disease-free period (or s	urvival) in patien	seek evidence for an increase in the nts with Duke's "B2" or "C" Colorectal ds with a platelet inhibitory agent-aspirin.
TECHNICAL APPROACH: A coagui	ation screen , fac	ctor VIII complex. Salicylate level
and platelet function tes to treatment and one mont	ts (aggregation an h post treatment.	nd membrane analysis) will be done prior The patients will then be followed - below
PROGRESS DURING FY-82: Slow a	ccural with only	11 patients entered to date follows
up adequate on 10 of the	se. One patient di	ll patients entered to date. follow- ied of progressive disease and one
NUMBER OF SUBJECTS STUDIED: Par	st vear. Study Clo	till living.No Toxicity reported in the osed 10/81- 2/11 have expired-8/11 have
FY-82: 0 Total	table disease and (TO DATE): 11	1/11 is lost to follow-up. BEFORE COMPLETION OF STUDY: closed
SERIOUS/UNEXPECTED SIDE EFFECTS	IN SUBJECTS PARTICIPAT	TING IN PROJECT(IF HOME SO STATE):
NONE		
CONCLUSIONS: Inadquate number	er of entries and	follow-up interval for assesment.
PUBLICATIONS OR ABSTRACTS, FY-8	2:	
	NONE	

Technical Approach: (continued) according to the protocol with subsequent coagulation studies at 4-month intervals or whenever bleeding or Thrombosis appears.

DATE: 10/2/82	HOPK WHIT N	o.: 1673	STATUS	INTERIM X	Free	
STARTILE DATE:	5/79	DATE	OF COMPLET	10м:	· · · · · · · · · · · · · · · · · · ·	
Key Words: Testicular Cancer Stage I and II						
Time of Project: TC - 179 - Treatment of Stage I/II Testicular carcinoma with Vinblastine, Actinomycin, Cyclophosphamide, Bleomycin, and Cis-Platinum. Testicular Cancef Intergroup Study.						
PRINCIPAL INVESTIG	GATOR(S):	Raymond B. Weis	s.M.D.	······································		
ASSOCIATE INVESTI	GATOR(S):					
FACILITY: WRANC		DEPT/Syc: Hema	tology/	Oncology - D	ept. Of Med.	
ACCUMULATIVE PEDC	ASE Cost:	ACCUMPLATIVE CONTRAC	r Cost:	ACCUMULATIVE S	SUPPLY COST:	
FY-83 i EDCASE: 00	CONTRACT COS	T: SUPPLY COST:	DATE OF	COMITTEE APPROPRIES REPORT	PEB 2 5. 1923	
Story Osjective: 1. Compare the disease -free survival and overall survival for surgery alone versus surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular Carcinoma. 2. To registar and follow OVER TECHNICAL APPROACH: All stage I patients will be registered then followed by monthly markers and chest X-rays for 1 year and then every 2 months for another year. All Stage II patients will be randomized to no adjuvant - see back						
Stage I and	4 have now	te 15 patients ha completed their O patients are St	2 vear	period of ob:	servation, and	d, -ower
Number of sub			-			
FY-82: 1	Total	(TO DATE): 15	BEFO	RE COMPLETION OF	STUDY: 200	
SPRIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE): NONE						
Community Strategy adjuvant chem of progressiv	notherapy i	at for those pations of the secessary in or	ents wit der to	h stage II , prevent the p	Disease , cossibility	
Publications on As	ISTRACTS. FY-S	32:				

None

Study Objectives :patients with non-schinoma, non-Choriocarcinoma Stage I testicular cancer to define prognostic variables which may predict recurrence in this stage group.

- 3. To define differences in disease free rates and patterns of recurrence based on histologic subtypes.
- 4. Evaluate role of marker substances I.E., BHCG, AFP, And LDH in the early detection and management of recurrences.
- 5. Evaluate accuracy of Lymphangiograms, CT scans, and ultrasound studies for staging of retroperitomeal nodal involvement.

Tech; Approach cont'd.: chemotherapy or to adjuvant chemotherapy. Those receiving adjuvant chemotherapy will receive Cytoxan, Actinomycin, Vinblastine on day 11 Bleomycin on days 1 through 6, and lastly, Cis-Platinum on day 7. This cycle of therapy will be repeated at 28 days. Two cycles only will be given then follow-up monthly for one year, then Bi-monthly for the next year.

Progress cont'd: randomozed to no adjuvant chemotherapy, subsquently developed prigressive disease and according to protocol were started on adjuvant chemopherapy. the remaining 6 stage II patients were randomized to adjuvant chemotherapy, have completed their chemotherapy, and are currently being followed here or off post. They are all well and free of disease.

DATE: 10/2/82	Mosk Burr No.:	_1674	STATUS	: Interin	First X	
STARTING DATE:	1978	DATE O	F CUMPLET	1011: 10)/8i	
Kay Moros: Ad	riamycin , Ind	ocvanine Green	L			
TITLE OF PROJECT:		BA: Effect of	Inodcya	nine Green	Clearence	
on Plasma leve	ls of Adriamyo	ein				
PRINCIPAL INVESTIG	Rayn	ond B. Weiss,	м.р.			
ASSOCIATE TOVESTION	SATOR(S):					
FACILITY: VRANC		Depr/Syc: Hen	natology	/ Oncology	-Dept. Of Med	d.
ACCUMULATIVE MEDICA	ASS COST: Acc	UMULATIVE CONTRACT	Cost:	ACCUMULATIN	VE SUPPLY COST:	
00		00	l D	00.		
FY-83 YEDCASE:00		Supply Cost:	PANUAL PANUAL	Committee <i>he</i> Paogress Repo	PROVAL UF DRT FEB 2 5 1983	}
STUDY OBJECTIVE: with plasma lev TECHNICAL APPROAGE tration of Adr permutations of PROSRESS FURING FUT to fact that o	els of Adriamy indocyanine iamycin. A tot f Liver dysfur 52Protocol c	Green clearer cal of 50 Indoorction, doseage	nce obta cyanine es of Ac it entry	nined prior analyses s driamycin ,	to first admi should allow fo , and clinical rate was very	inis- or all toxicity. slow due
ble. To date 1	5 pts' were er	itered at WRAM(C. All 6	<u>xperience</u>	l progressive	disease .
Number of Subjects	S STUDIED: [and] . This _	nave since e s is a finilaze	expired. Ed repor	No furthe	er patienss en <u>n Gr Stuby: Close</u>	tered FY82
FY-82:) 0	lorze (10	DATE): 15	BEFO	RE COMPLETION	i or alread: CIBS se	d
SERIOUS/UNEXPECTED	Side Effects in	SUBJECTS PARTICIPA	тиз и Р	יכוז TI)דסבעכה	NE SO STATE):	'
NON	E					•
CONCLUSIONS: Pat any diffinitive forth-coming.	conclusions.	Porotcol is ci	losed to	entry and	gressive to for i more data is	
PUBLICATIONS OR AS	BSTRACTS. FY-82:	<u>, , , , , , , , , , , , , , , , , , , </u>				-
	NONE					

DATE: 10/2/82 Now User No.:	1675	STATUS:	IRTER19	Fire X	
STARTING DATE: 1979	DATE OF	COMPLETION	i: 10/82		
Key Moras: Hepatic Artery A	driamycon Infusi	on			
Title of Project: WRAMC # 790 Pharmacokinetic study.	3 - Hepatic Art	ery infus	sion - a Clir	nical and	
PRINCIPAL INVESTIGATOR(S): Ray	mond B. Weiss, M	.D.			
ASSOCIATE INVESTIGATOR(S):					
FACILITY: WRANG	Depr/Syc:Hemato	logy/ One	cology - Dept	. Of Med.	
	ACCUMULATIVE CONTRACT	Cost: /	ACCUMULATIVE SUP	PLY COST:	
FY-83 PECCASE: CONTRACT COST:	00 SUPPLY (OST: 	DATE OF CO ANNUAL PRO	OO DIMITTEE PAROVA DERESS REPORT F	∟ 0 <i>=</i> EB 25 1983	
STUDY OSUBCTIVE: To evaluate to in patients with metastate Adriamy cin and its metabon TECHNICAL APPROACH: Special diametery and hepatic vein coine for 99 mtc sulfur co	ic liver disease lites.To correla gnostics will pl eatheter via femo	. To eval te the do ace Hepa oralvein.	luate the Pha ese response tic Artery ca Patient is	armacokinetics of with clinical- SEE atheter via axillary sent to nuclear medi-	-
PROGRESS DURING FY-82: No addi This is a finilazed repor	tional patients				
NUMBER OF SUBJECTS STUDIED:				·	
FY-82: 0 TOTAL (1	O DATE): 2	BEFORE	COMPLETION OF S	Tupçlosed	
SERIOUS/UNEXPECTED SIDE EFFECTS I	N SUBJECTS PARTICIPAT	THIS IN PROJ	JECT(1F NOME SO	STATE):	
Conclusions: Not enough patie closed.	nts entered, wit	hout furt	her accural	study being	
PUBLICATIONS OR ABSTRACTS, FY-82:	NONE				
Study Objective: (con scan, angiogram, and dysfunction.	tinued) toxio liver-spleen s	city. T seen as	Co evaluate parameters	e radiouclide s of liver	
Technical Approach: (blood flow distributi	continued)	catherer	placement	and hepatic	

DATE: 10/2/82	Noak Ever No	.: 1676	STATUS	: INTERIM X	Final	
STARTING DATE: 8/28/81 PATE OF COMMETTION:						
KEY KOPOS:	Colon Carci	noma				
		4 - Evaluation of	Carcin	e embroyonic A	ntigen and	
Second Look Sur	rgery in Co	lon Carcinoma.				
PRINCIPAL INVESTIG	GATOR(S): R	aymond B. Weiss, M	.D.			
Associate Investig	CATOR(s):		·			
FACILITY: NRANC		DEPT/S/c: Hemato	logy/0	ncology -Dept	.Of Med.	
ACCUMULATIVE MEBCA	ASE Cost:	Accumulative Contract 00	C037:	ACCUMULATIVE S	JPPLY COST:	
	CONTRACT COST	: Supply Cost:	DATE OF	COMMITTEE PARCE	val Oa	
00	00	00	FINUAL	PROGRESS REPORT	EE3 85 1020	
Laporatomy as	a method o	rial serum C&A lev f detecting recurr at high risk of re	ent di	sease early.	-	
and CEA every 3	noma are in months. Wh	at high risk of re followed by clinic nen CEA rises comp	al exa lete r	m, routine ble e-evaluation	ood chemist for recurre	ries, nce ,(below)
PROGRESS FURING FY 2 pts. have he	<u> १६२</u> : Total ad pd and h	of 18 patients ent ave expired. 2 pts	ered b	efore Protoco rwent explora	l closure l	.0/81 atomy.
Мымвек ол Ѕизивств	STUDIED:		···			
FY-82: 0	TOTAL ((TO DATE): 18	_ Befor	RE COMPLETION OF	Study: close	ed.
	SIDE EFFECTS	IN SUBJECTS PARTICIPATI	ns in Pr	ROUECT(IF HONE SC	STATE):	
NONE Conclusions: Inc	adequate fo	llow-up ti me and	number	of entries t	o analyze	
data.	-aoquato to	220# Op C2 mc dita		or cherics c	o analyze	
Publications of As	STANCES EV. 92					
FUSICION FORS OF AS		: ONE				
	M	ONE				

Technical Approach: (continued) including Paparotomy is undertaken to determine respectability of recurrence.

DATE: 10-2-82 Now UNIT 18	o.: 1677	STATUS: INTERIM	Fire, X
STARTING DATE: 9/25/79	DATE OF	COMPLETION: 1982	Million age recommendate the million age of the se
Key Ropos: Acute Leukemia	<u> </u>		
TITLE OF PROJECT: WRAMC # 7		ite Leukemia with	low dose Adriamycin
Infusiona			
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss, N	1.D	
ASSOCIATE INVESTIGATOR(S):			
FACILITY: MRANC	DEPT/SVC: Hemato	ology /Oncology - I	Dept. Of Med.
Accumunative MEDCASE Cost: 00	ACCUMULATIVE CONTRACT C	OST: ACCUMULATIVE S	SUPPLY COST:
FY-83 PEDCASE: CONTRACT COS 0-0= 00	00	Date of Countries Appen MANUAL PROSSESS REPORT	Mark Dog As
STUDY OBJECTIVE To determine would change it's effica cycline therapy. TECHNICAL APPROACH: TRN dose possible escalation if the state of	e if kinetic alterated in advanced Leuk	temia patients pres mycon 10mg/m2/day	viously failing Anthra-
REGRESS DURING FY-82: Total patient accural. To date	ils by FACS. accural of 5 patier	its . Study closed	10-81 No further
Number of Subjects Studied:			
FY-82: O TOTAL	(TO DATE): 5	BEFORE COMPLETION OF	STUDY: closed
Serious/Unexpected Side Effects Severe Mucosi		ns in Papuact(in homa s	O STATE):
Conclusions: Date too spa	rse- no conclusion.		
PUBLICATIONS OR ABSTRACTS, FY-8	32:		The state of the s
NONE			

DATE: 10/2/82 HOPK UNIT N	o.: 1678	STATUS: INTERIM	Frizi, x
START INS DATE: 9/25/79	DATE OF	COMPLETION: 10/82	
KEY WORDS: Metastatic Col	o-Rectal Carcinoma		
TITLE OF PROJECT: WRAMC:#	7914 - Metastatic (Colo-Rectal Carcino	ma
			
PRINCIPAL INVESTIGATOR(S): D	evid J. Perry, M.D.	•	
ASSOCIATE INVESTIGATOR(S):			
FACILITY: HRANC	DEPT/Svc: Hema	atology/ Oncology -	Dept.OF med
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE S	UPPLY COST:
00	00	<u></u>	
FY-83 i EDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPRO ANNUAL PROGRESS REPORT	VAL 0= FEB 2 5 1997
STUDY OBJECTIVE: To investi in Advanced measurable			ptozotocin
TECHNICAL APPROACH: 5-Fouoro ning on day 1. Repeat e ive days beginning on d	uracil 300mg/m2//IV very 35 days. Methy av 2. Repeat every	/ daily for 5 conse /1 CCNU 30mg/m2 po // days. Vincristi	cutive days, begin- daily for 5 consect- ne lmg/IV push dayl.(be-
PROGRESS DURING FY-82: Proto 5 patients alive, 48 p	col Closed ,10/81.		
Number of Subjects Studied:			
FY-82: 0 TOTAL	(TO DATE): 53	BEFORE COMPLETION OF	STUDY: 53
SERIOUS/UNEXPECTED SADE EFFECTS NONE	S IN SUBJECTS PARTICIPATI	nns in Papusot(is none s	O STATE):
Conceusions: 2/50 (4%) CR,	9/50 (18%) PR CR+	PR = 22%. Of 40 pat	ients previouslu
intreated with chemothera	py .10/40 (25&) res	ponded. Median dura	tion PR 122 days
42 -490) CR 169 +466 day 41 days(P=0.03,,log rank	ys. Median survival	responders 424 day	s., non-responders
cate and more toxic than	5FU alone. Need ran	domized study to	le same response hetter assess
fficacy.			
PUBLICATIONS OR ABSTRACTS, FY-8	32:		

Submitted for publication to <u>Journal of Clinical Oncology</u>

Funds needed for reprints. 250.00.

Technical Approach: (continued) repeat every 35 days. Strepto-zotocin 500~mg/m2 IV weekly beginning on day 1. Two complete courses should be given to fully evaluate efficacy of regimen. If there is progression of measurable disease after 2 courses or any time thereafter, the patient is removed from protocol and followed for survival information.

DATE: 10/2/82 NOR LINE II	o.: 1679	STATUS: INTERIM	Final X			
STARTING DATE: 10-79 DATE OF COMPLETION: 10-81						
KEY NORDS: Melanoma, Co	olon and Gastric C	ancer	***			
TITLE OF PROJECT: WRANC :#	7907 - Use of Met Melanoma,	hyl CCNU in the To	reatment of C Cancer			
PRINCIPAL INVESTIGATOR(S): R	aymond B. Weiss,	M.D.				
ASSOCIATE INVESTIGATOR(S):			The second section and the second sec			
FACILITY: VRANC	DEPT/SVC: He	matology/ Oncology	- Dept. Of Med.			
ACCUMULATIVE NEDCASE COST: 00	ACCUMULATIVE CONTRACT	r Cost: Accumulativ 00	VE SUPPLY COST:			
FY-83 PERCASE: CONTRACT COS	T: SUPPLY GOST:	DATE OF COMMITTEE AGENCY PROBLEMS REPORTED TO ANNUAL PROGRESS REPORTED TO ANNUAL PROGR	PROVAL 0.5 DRT FEB 2.5 1983			
STUDY OBJECTIVE: The Nitroso ally synthesized anticance although they possess som TECHNICAL APPROACH: Methyl OF PROSRESS DURING FY-82: To defend 3 still have stable	e biologic proper CCNU (Semustine):	ties of alkylating 200 mg/m2 po eye: 'e been entered, 3	ry 6-8 weeks.			
Number of Subjects Studied:			***************************************			
FY-82: 0 TOTAL	(TO DATE): 6	BEFORE COMPLETION	Closed			
Sartous/Unexpected Side Effect NONE	s in Subjects Particip.	AFING IN PROJECT(IF NO:	E SO STATE):			
CONCLUSIONS: Methyl CCNU h tory to other agents.	as some efficacy	in patients previo	usly refrac-			
PUBLICATIONS OR ABSTRACTS, FY-S	82:					
Study Objective: (e.	~~+ d ~	. h h				

Study Objective: (continued) they have high lipid solubility and are known to cross the blood-brain barrier. They are highly active cytotoxic agents in a number of animal tumor systems. Clinical studies with Methyl CCNU have been ongoing since 1971, Methyl CCNU has shown activity as a single agent in the treatment Melanoma. Minimal activity in colon and gastric cancer, has been seen with Methyl CCNU as a single agent, but in combination with 3-FU some trials reported the efficacy is increased.

DATE: 10-2/82 Now Unit II	o.: 1680	SINTUS	: INTERIM	Firm X	_
STARTING DATE: 10-79	DATE OF	- (००५ हा	10:1: 10-82		-
Key Nows: Islet Cell Care					~
TITLE OF PROJECT: WRAMC #	7908 Use of Strep	to zo to	in in the tr	eatment of	
metastatic Islet cell Car	rcin oma of the pa	ncreas	and metastat	ic carcinol	d.
				· · · · · · · · · · · · · · · · · · ·	~
PRINCIPAL INVESTIGATOR(s):	Raymond B, Weiss	, M.D.			-
ASSOCIATE INVESTIGATOR(S):					-
FACILITY: NRAYC	DEPT/SVC: Hem	atolog	/ Oncodogy -	-Dept. Of me	.d.
ACCUMULATIVE MEDCASE COST:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE	SUPPLY COST:	-
00	00		00		_
FY-83 PEDCASE: CONTRACT COST	T: SUPPLY COST:	PATE OF FINNUAL	COMMITTEE APPR PROGRESS REPORT	OVAL OF FER 85 1833	-
Study Osusctiva: Streptozoto	ocin has shown a g	reat de	oree of effe	ctiveness f	= mot
astatic Islet Cell carcin	noma of the Pancre	as and	metastatic o	arcinoid. C	linical
TECHNICAL APPROACH: Strepto					FF below.
soth a five day intensi	ve course regimen	and a r	reekly regime	en have been	widelv
employed using this drug	g, with current fa	yor giv	en to a sche	dule of 500	mg/m2 IV ove
PROGRESS DURING FY-82: Fou on therapy. no furtherpa	r patients were li tiens have been en	sted o	n this study This is a f	. All havedi inalized rep	ed while ort.
Number of Subjects Studied:		***			-
FY-82: TOTAL	(TO DATE): 4	BEFO	RE COMPLETION O	F STUDY <u>: Clo</u>	sed
SERIOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPAL	ring in F	ROUECT(IF NOME	SO STATE):	-
Significant :	neausea in all pat	eints.	One patient	developed	severe
Conclusions:		·			musositis.
No	ONE				
PUBLICATIONS OF ABSTRACTS, FY-S	20.				_
PUBLICATIONS OR ABSTRACTS, F1-3	NONE				
	NONE				
Study Objective: (
patients with malig					yields
an overall response objective response		rwate	1y /0%. E	ven ir an	

Technical Approach: (continued) Bolus dao; u x 5 everu 6 weels/ The weekly schedule has usually been 1 mg/m2 x 4 weeks.

DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-MH

WRAMC #7908

Protocol #1680

To Dr Timothy M. Boehm

FROM Raymond B. Weiss

DATE 8 Oct 82

CMT 1

Chief, Dept of Clin Inv

Med/Onc

WRAMC Protocol #7908 was a "convenience" protocol for use of the drug strepozocin which was one of the group C drugs supplied by the NCI. This drug has now been approved by the FDA for marketing and thus there is no longer any need for a protocol #7908 is now officially closed.

Chief

Section of Medical Oncology

Title of Protocol: WRAMC #7908, Use of Streptozotocin in the Treatment of Metastatic Islet Cell Carcinoma

(Group C Drug).

DATE: 10-2-82 WORK UNIT NO.: 1681	STATUS: INTERIM FIRE X
	E OF COMPLETION: 10-81
Key loos: Leukemia in Adults and Childre	en
TITLE OF PROJECT: WRAMC # 7909 - Use of Data and other Leukemias in Adults and child	
PRINCIPAL INVESTIGATOR(S): Howard Terebelo	, M.D.
ASSOCIATE INVESTIGATOR(S): Raymond B. Weis	s. M.D. Chief Medical Oncology
FACILITY: WRANC DEPT/SycHema	tology/Oncology- Dept. Of Med.
ACCUMULATIVE PEDCASE COST: ACCUMULATIVE CONTR	ACT COST: ACCUMULATIVE SUPPLY COST:
FY-83 PECCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF FAMOUAL PROGRESS REPORT FEB 2.5 1983
STUDY OBJECTIVE: Danuomycin is known by se they include Danuorubicine, Rubidomycin	veral other names. For information purposes, C, Cerutidine and NSC 82151.
a single agent is 60mg/m2 day 1 IV for intervals of three to six weeks. depend PROUNTESS DURING FY-82: [counts [prog:	ed dosage of Banuomycin when it is used as theee Days. the course is usually repeated at ing on the status of bone marrow and periphera 6 patients entered in 1980-81 - 4 died/
l patient is too early: l patient is al Study closed 10/81. Prior to it's closur	ive with M2 marrow (Partial Response). e, a total of 6 pts. were entered. to date all
Number of Subjects Studied: [this is a final	
FY-82: 0 TOTAL (TO DATE): 6	BEFORE COMPLETION OF STUDY: closed
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTIC NONE	IPATING IN PROJECT(IF NOME SO STATE):
CONCLUSIONS: This agent DNR is of proven e availability in those patents refusing o	fficacy for Acute Leukemia. It provides r ineligible for CALGB studies.
PUBLICATIONS OR ABSTRACTS, FY-82:	

			
DATE: 10-2-82 HOPK UNIT II	o.: 1682	STATUS: INTERIM X	Final
STARTING DATE: 10-79	DATE OF	COMPLETION:	
KEY NOPOS: Acute Granulo	ocytic Leukemia in	Adults and Childre	1
TITLE OF PROJECT: WRAMC # 79 Acute Graunlocytic Leuke	10- Use of 5 azacy mia in Adults and (ytidine in the tre	eatment of
PRINCIPAL INVESTIGATOR(S):	Raymond B. Weiss. N	M.d.	
ASSOCIATE INVESTIGATOR(S):			
FACILITY: WRAYE	DEPT/Syc: Hema	atology/ Oncology -	Dept.Of Med.
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT (SUPPLY COST:
00 FY-83 PEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPROACH PROGRESS REPORT	FEB 2 5 June 1
STUDY USJECTIVE: At tis poi effectiveness for the in Adults and Children prev TECHNICAL APPROACH: Respons See Back; Inot been PROGRESS BURING FY-82: No phave been entered. Both	duction of remission of remissi	on in Acute Granulo to other active and umors and other type arrant the use of 5	cytic Leukemia of i-Leukemia drugs. bes of Leukemia have i-Azacytidine. (below) but no further patients
Mumber of Subjects Studied:			
FY-82: 0 TOTAL	(TO DATE): 2	BEFORE COMPLETION OF	: STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	S IN SUBJECTS PARTICIPATI	ING IN PROJECT(IF NOWE S	SO STATE):
Conclusions: 5-Azacytiding in 2 patients here. It refractory patients.	e is effective in 3 remains an effecti	0% of Leukemia, n ve agent it shoul	o response documented d be available for
PUBLICATIONS OR ABSTRACTS. FY-8	12:		
NONE			

Techical Approach: (continued) 150-200 mg/m2/day intravenously for 5 days as a rapid injection. This drug course can be repeated every day 14-15 days, depending upon recovery from myelosuppression and the bone marrow findings.

DATE: 10-2-82 HOOK UNIT IN	0.: 1683	STATUS: INTERIM	Final_X				
STARTING DATE: 10-79	DATE OF	COMPLETION: 10	-8.2:				
Key Webs: L-Asparaginas	e in treatment of	Leukemia in Adult	s and Children				
TITLE OF PROJECT: WRAMC # 7911 - Use of L- Asparaginase in the treatment of Acute Lymphoblastic Leukemia in Adults and Children							
PRINCIPAL INVESTIGATOR(S): Howard Terebelo, M.D.							
ASSOCIATE INVESTIGATOR(S):	ASSOCIATE INVESTIGATOR(s): Raymond B. Weiss, MD.Chief of Medical Oncology						
FACILITY: HRAYC	`	ology/Oncology-De					
Accumurative MEDCASE Cost:	ACCUMBATIVE CONTRACT	Cost: AccumuLativ					
FY-83 PEDCASE: CONTRACT COS		DATE OF COMMITTEE AS ANNUAL PROGRESS REPO	PROVAL OF DRT FEB 2 5 1983				
STUDY OBJECTIVE: Erwina Car active Asparaginase. It in both animal tumor sys	y is qualitatively	and quantitative	ally non-cross rethe E. Coli preparation E.Coli Asparaginase is by the same. Therefore Coli Asparaginase in	1 ts			
See helow [those si	tustions where ren	eat coursed thera	my are required or when	re			
PROGRESS DURING FY-Spallergi	c reactions force	the discontinuand	ce of the E. Coll prep-				
See below.							
MUMBER OF SUBJECTS STUDIED:							
FY-82: 0 TOTAL	(TO DATE): 0	BEFORE COMPLETION	of Study: Closed				
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPAT	TING IN PROJECT(IF NO	SE SO STATE):				
CONCLUSIONS: NONE							
HOULE							
PUBLICATIONS OR ABSTRACTS. FY-	82:		· · · · · · · · · · · · · · · · · · ·				
NONE							
Technical Approach: x 10-20 days. Intra	(continued) In muscularly 6,00	travenously 1, O IU/m2 T.I.W.	000 IU/m2 per day x 3 weeks (9 doses	:).			
Progress During FY-8 protocol was opened. finalized report.	2: No patien It was subseq	ts entered at uently closed	WRAMC since this 10/81. This is a				

DATE: 10.2.82	HORK UNIT NO .:	1684	STATUS	HTERIM	FINAL X	
STARTING DATE:	Oct. 79	DATE	OF COMPLETE	ION: 10/82		
KEY HORDS: OT	varian Cancer					
Time of Project." of Ovarian Ca		2 - Use of Hex	ameh ty 1me	elamine in t	he treatm	ent
PRINCIPAL INVESTI	GATOR(S): Raym	ond. B. Weiss.	M.D.		~~~~~~	
ASSCRIATE INVESTE	GATOR(S):				 -	
FACILITY: HRAYE		DEPT/SVC: Her	matology/	Oncology -	Dept. Of M	ed.
Accumulative iEOC	ASE Cost: A	COUNTRATIVE CONTRA	cr Cost:	ACCUMULATIVE	SUPPLY COST:	-
00		00		<u> </u>		
FY-83 PEDCASE:	CONTRACT COST:	Supply Cost:	DATE OF ANNUAL P	COMITTEE APPL POGRESS REPORT	COVAL OF FEB 25 1	98 3
TECHNICAL APPROACE PROSEES DURING F (less than 2	Finite antitude: 21 days (8) $\frac{Y-82}{000/mm3}$	e ovary is the mor activity. mg/kg day) or should be stor severe throm	opped in	lays off dru the presence tha (less the	e of sever	
until marrow	function has	recovered.Clc	sed 10/82	This is	_ finalized	_re
FY-82: 0		DATE): 0	BEFOR	RE COMPLETION O	DE STUBY: C1	.cse
SPRIOUS/UNEXPECTE	D SIDE EFFECTS IN	N SUBJECTS PARTICI	PATING IN PA	באכון או אום אב	SO STATE):	
Cr						
	NONE					
						
FUEL CATIONS OR A	BSTRACTS. FY-52:					

DATE: 10/2/82	HORK UNIT NO.:	1685	STATUS	: INTERIM y FINAL	_
STARTILE DATE:	10/79	DATE O	F COMPLET	ION:	_
Key Mords: Small	Cell Carci	noma Lung			_
TITLE OF PROJECT:	WRAMC ;# 79	13 - Use of VP- Cell Carci	16 in t noma of	he Treatment of Small the Lung.	_
PRINCIPAL INVESTIGA		aymond B. Weiss	,M.D.		<u>-</u>
ASSOCIATE INVESTIGA	TOR(S):				-
FACILITY: WRAYE		DEPT/Svc:Hemat	ology/	Oncology - Dept. Of Med.	• =
Accumulative PEDCAS	E Cost: A	CCUMULATIVE CONTRACT	· Cost:	ACCUMULATIVE SUPPLY COST:	
FY-83 PEDCASE: C	ONTRACT COST:	Supply Cost:	DATE OF ANNUAL	COMMITTEE APPROVAL OF PROGRESS REPORT FEB 25 1983	- -
TECHNICAL APPROACH:	VP-16 213	should be admir	istered	ponses in previously 6% in the treatment of strecommendation is that is intravenously over a successfully. 60mg/m2/daveeks. The exact interva	30-
PROGRESS BURING FY-	<u>82</u> : 6 pati			and all 6 have expired.	-
Number of Subjects (_		
FY-82 <u>: 0</u>	IOTAL (TO	D DATE): 6	Befo	RE COMPLETION OF STUDY: 30	_
	Side Effects in	N SUBJECTS PARTICIPA	TING IN P	ROJECT(IF MONE SO STATE):	-
CONCLUSIONS: Inac be kept open for	lequate numb future pat	per of entries in the state of entry.	or eval	uation. Recommend proto	- col
PUBLICATIONS OR ABST	TRACTS. FY-82:	 			_
NONE					
tory to "stan	dard ther	apy" for this	s dise.	imited to patients rase. Experimental din previously untre	lata

Technical Approach: (continued) subsequent courses are modified depending upon the time required from toxic manifestations.

DATE: 10-2 82	MORK UNIT NO	: 1686	STATUS	S: INTERIM	Fire	<u> </u>
STARTING DATE:		D.	ATE OF COMPLET	rich: 81		
KEY HORDS: Hodg	kin's dise	ase or NHC		·		
TITLE OF PROJECT: with combination	WRAMC # 79 on Chempthe	15 - Preventi rapy for Hodg	on of Gonac kin's Disea	dal Damage i ase or NHC.	in Women t	reated
PRINCIPAL INVESTIGA		ymond B. Weis:	s, M.D.			
FACILITY: WRAYC	34102(37.	DEPT/SVC: H	ematology/	Oncology- I	ept. Of M	led.
Accumulative PEOC	SE Cost:	ACCUMULATIVE CON		~		
FY-83 PEDCASE:	CONTRACT COST	SUPPLY COST:	DATE OF ANNUAL	COMMITTEE APP PROGRESS REPOR	PROVAL OF FEB 25	100:
STUDY OBJECTIVE:	To protect of Hodgkin's D	women from Ove Lsease or non-	arian failu - H_D .Lymp	ure 20 chemo phoma.	therapy f	or
TECHNICAL APPROACE a control with	Randomiz	e to receive o	combined or	cal contrace	ptives or	serve as
PROGRESS BURING FY	<u>'-82</u> : Study repor	closed. No pa	atients ent	ered. this	is a Fina	lized
MUMBER OF SUBJECTS	: אינונם:					
FY-82 <u>: 0</u>	TOTAL (TO DATE):	BEFO	RE COMPLETION	o= Sτυργ <u>:</u>	<u>clos</u> ed
SERIOUS/UNEXPECTED NONE	SIDE EFFECTS	IN SUBJECTS PARTI	CIPATING IN P	ROUECT(IF NONE	SO STATE):	
CONCLUSIONS: Pritinued here at		stigator was	reassigned	. Study will	l no longe	er be con-
PUBLICATIONS OR AB	STRACTS, FY-82	:				Portugue.

DATE: 10-2082 STARTING DATE: 2/	HORK UNIT NO.		STATUS:		x From	
						
KEY KORDS: Met	IL G for Hea	d and Neck Carcin	loma	e Washerl	Classical	Pda Cuarrel
Tine of Project: Hydrazone €Methy	71 -GAG) in	02 - Phase LL eva advanced Esophage	eal Carci	noma , He	ad and Nec	ck.
PRINCIPAL INVESTIG	PATOR(S):	David Perry, M.D		·		····
ASSOCIATE INVESTIG	GATOR(S):	Raymond B. Weiss.	M.D. C	hief , Me	dical Onco	ology
FACILITY: WRANC		DEPT/SVC: Hemato	ology/Onc	ology - D	ept.Of Me	<u>d.</u>
ACCUMULATIVE MEDO	ASE Cost:	ACCUMULATIVE CONTRACT	Cost: A	CCUMULATIVE 00	SUPPLY COST	r:
FY-83 i EDCASE:	CONTRACT COST:	Supply Cost:	DATE OF CO ANNUAL PRO	YMITTEE APP GRESS REPOR	roval 0; t FEB 25	1983
STUDY USJECTIVE: weekly schedule and Neck car	of Methyl-G	he response rate AG in patients wi rix	and remi	ssion dur ced Esoph	ation utla ageal Card	lzing a cinoma.
TECHNICAL APPROACH d5w or normal	: Methyo -G saline over	500mg/m2, to be no less than 30	given as minutes,	an intra into a f	venous inf reely run	fusion ning IV.
Prosess Busing Fy evaluable patien 17 days median s	<u>/-82</u> : 26 patients) .2/22 0 survival) 23	ents entered total R, 8/22PR, CR+PR Q day moderately	l. 9 duri = 41% me severe n	ng 82. He dian dura ausea and	ad and Nection of revowiting	ck (22- emission and anemia,
Number of Subjects	STUDIED (Impr	oved with 82 week	schedul	e. Patien	ts with lu	ing cancer (2)
FY-82 <u>: g</u>	Total (esophageal cance	DEFORE	d not resp	or Sluck: Cl	losed
SERIOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS PARTICIPAT	ins in Proj	ECT(1F NONE	SO STATE):	
NONE						
CONCLUSIOMS: Meth	nyl G has ac	tivity in head an	id neck c	ancer. The	e study is	closed.

Publications or Abstracts, FY-82: ?resented in abstract form at Army - Hematology - Oncology meeting Feb. 82. Paper submitted for publication to Cancer Treatment Reports Need \$150.00 for reprints.

PATE: 10-2-82	Mass Curt R	1690	Statu	s: Interin X	Fire	
Stanting Date: 4	-80	<u>Data c</u>	- (cm:17	rten:		
May Nows: Adv	anced Test	icular Cancer				
Time or Paguact: With VP16-213	WRAMC # 80	03 - Treatment Of	Advanc	ed Testicular	Cancer	
		ymond R. Weiss, M. . Grant Taylor, M.			···	
FACILITY: MRAYC		DEPT/SVC: Hemat			t. Of Med.	•
ACCUMULATIVE PEDC	ASE Cost:	ACCUMPLATIVE CONTRACT		a.		:
FY-83 PERCASE:		T: Supply Cost:	DATE OF	COUNTTEE APPRI PROGRESS REPORT	FEB 2 5 1981	3
Study Objective:	4102000	activity of Combo, l neoplasmas.	Chemo t	nerapy in RX	of Advanced	
TECHNICAL ÉVERONO	Cytoxan IV q 6	, Velban, Actino-1), Bleo	, DDP, VP-16,	VCR,	
Paggras Paggs F violation. All responders 6	patients	ients entered on s have achieved a pa quired surgery aft	cudy,	one of whom w	as a protoco re are 11 co	ol omplete
Normes on Cusucon	s Sಗರ್ಭವ:			A LO LIE	M. CITETE ITE	/e ~ (0010m)
FY-92: 10	Total	(TO DA.E): 24	Ваяс	ORE COMPLETION OF	F Sruey: 50	
	SIDE EFFECTS	S III SUBJECTS PARTICIPA	Ting in f	PADUECT(IF HONE !	STATE):	
Concustons:	Too earl	y for conclusions				
FUEL ICATIONS OR AS	STRACTS. FY-8	22:			-	•

Progress during FY-82 continued: been 2 deaths in patients with advanced disease.

DATE: 10-2-82	HORK BULT NO	.: 1691	STATUS	INTERIM	FIRM X				
STARTILES DATE: 3-80 DATE OF COMPLETION: 10-82									
Key Words:	Key Words: Monocyte, Sarcoidosis								
	VINE CF PROJECT: WRAMC #8004 Monocyte Function in Peripheral Blood and Bone Marrow in Patients with Sarcoidosis								
		C., H. Grant Taylo		•					
	GATOR(S): K	aymond B. Weiss, M		Dept. of Me	4				
FACILITY: KRAYC									
ACCUMULATIVE PEDC	ASE Cost:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE	SUPPLY COST:				
00 FY-83 #EDCASE: 00	CONTRACT COST	OO : Supply Cost: OO	DATE OF	Committee Appa Progress Report	ROVAL OF FER 2.5 1983				
Show Objective. Demonstrate methods of evaluating peripheral blood monocyte activation. 2. Demonstrate relationship between BM phagocytosis and monocyte function. TECHNICAL APPROACH: Numerical evaluation of phagocytic activity in bone marrow aspirates to be correlated with Mitogen transformation potention of peripheral blood monocytes.									
Prosess During F No further p		ve been entered. S	tudy h	as been close	ed to patient e	ntry 10-81.			
Hursen of Subjects	S STUDIED:								
Ł. 85 0	Total	(TO DATE): 5	Befo	RE COMPLETION O	STUDY Closed				
SERIOUS/UNEXPECTED	D SIDE EFFECTS	IN SUBJECTS PARTICIPAT	ing in P	ROJECT(15 HONE	SO STATE):				
None									
anoth eview was made	er area and of bone man	involved in assess d no data was gath rrow specimens per is increased in s	ered of formed	n monocyte acon on patients	ctivation. A r with sarcoidos	etrospective is. Bone			
Publications on As			ah T-	town Mod 1	62. 670. 1082				

			
DATE: 10/2/82 HOPK GULT N	o.: 1692	STATUS: INTERIM X	FIRM
STARTING DATE: April , 19	980 DATE C	F COMPLETION:	
Key Koros: Sodium Salt of	f Allopurinol to C	ontrol Hyperuricemia	3.
Title of Project: WRAMC:# 8 Hypericemia in patients w Protocol No. 78-099).	8005 - Use of Sodi	um Salt of Allopuri	nol to control
PRINCIPAL INVESTIGATOR(S):	James Wilson, MAJ.	MSC	
	•	.D. Chief, Medical (Oncology Servic
FACILITY: WRANG		atology/ Oncology -	
ACCUMULATIVE MEDCASE COST:	ACCUMULATIVE CONTRACT	·	
FY-83 FEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPR ANNUAL PROGRESS REPORT	CVAL D= 2 5 1983
STUDY USUBCTIVE: Determine of Hyperuricemia patient's intake is restricted. TECHNICAL APPROACH: IV Allop		nol is required and	
PROGRESS DURING FY-82: Three three patients.	patients entered	on study. Drug was	effective in
Number of Subjects Studied:		······································	_
FY-82: 2 Total	(TO DATE): 8.	BEFORE COMPLETION O	F STUDY:
Serious/Unexpected Side Effects No serious/	s in Subjects Participa / unexpected side		SO STATE):
Conclusions: A treatment the use of the drug was e	protocol to make effective in all c	availabel an investi ases.	igational drug.
Publications on Abstracts, FY-6	32:		

DATE: 10/2/82 HORK WHIT N	o.: 1693	STATUS: INTERIM Y FINAL
STARTING DATE: 5/80	DATE OF	COMPLETION:
Key Words: Oral Candidia	sis Prophylaxis	· · · · · · · · · · · · · · · · · · ·
TITLE OF PROJECT: WRAMC:# 8	006 - Clotrimazole	Prophylaxis of Oral Candidiasis.
PRINCIPAL INVESTIGATOR(S):	James Wilson, MAJ.	MSC
ASSOCIATE INVESTIGATOR(S):	Raymond R. Weiss	M.D. Chief , Medical Oncology
FACILITY: MRAYE	DEPT/Svc: Hemato	logy/ Oncology - Dept. Of Med.
ACCUMPLATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT C	
FY-83 PEDCASE: CONTRACT COS	T: Supply Cost: QQ	DATE OF COMMITTEE REPROVAL OF ANNUAL PROGRESS REPORT FEB 2.5 1083
STUDY USUSCTIVE: 1. Determine for oral Candidiasis.	ne the efficacy of	Clotrimazole as a prophylactic RX
TECHNICAL APPROACH: Double : troches		mazole troches 10mg vs. placebo
PROSRESS DURING FY-82: 13 pa	tients entered on s	tudy to date. and 1 in 82.
HUMBER OF SUBJECTS STUDIED:		
FY-82: 1 TOTAL	(TO DATE): 14	BEFORE COMPLETION OF STUDY: 50
SERIOUS/UMEXPECTED SIDE EFFECTS NONE	S IN SUBJECTS PARTICIPATIO	NG IN PROJECT(IF NONE SO STATE):
not broken on drug ident:	ents entered to date ity. Another protoco sume protocol 9/1/82	e to evaluate results. Also, code of had higher priority for these
PUBLICATIONS OR ABSTRACTS, FY-E	2:	

none

DATE: 10/2/82 MORK UNIT NO.: 1694	STATUS: INTERIM X FIRM
START INS DATE: 5/80 DATE OF	Completion:
KEY WORDS: Oral Candidiasis Treatment Clo	
TITLE OF PROJECT: WRAMC:# 8008 - Treatment of	Oral Candidiasis with Clotrimageole
	·
PRINCIPAL INVESTIGATOR(S): James Wilson, MAJ.	MSC
/ >	
	(.D. Chief Medical Oncology Ser. atology/ ONCOLOGY _ Depte Of MED.
ACCUMULATIVE NEDCASE COST: ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:
00 00	00
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF 2 5 1983
STUDY OBJECTIVE: Determine efficacy of Clots	rimazole in the treatment of Oropharyngeal
Candidiasis.	
TECHNICAL APPROACH: Clotrimazole troches 10mgm	1 5 x day/ 14 days
PROGRESS DURING FY-82: Four patients entered	
One patient withdrew on day two of study., Icaate in unknown research. Data collection	
Munsea of Suspects Studied:	Incomplete on 1 pacteurs
FY-82: 4 TOTAL (TO DATE): 4	BEFORE COMPLETION OF STUDY: 50
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPAT NONE	ING IN PROJECT(IF NONE SO STATE):
CONCLUSIONS: Too few patients entered to dat	te to evaluate results.
PUBLICATIONS OR ABSTRACTS, FY-82:	
NONE	•

DATE: 10/2/82 HORK UNIT NO.: 1695	STATUS: INTERIM & FINAL
	E OF COMPLETION:
Key lords: Oral Candidiasis Failure C	lotrimazole Study.
TITLE CF PROJECT: WRAMC:# 8007 - Clotrima in patients who fail the Clotrimazole P	zole treatment of Oral Candidiasis rophylaxis Study.
PRINCIPAL INVESTIGATOR(S): James Wilson, M	AJ. MSC
ASSOCIATE INVESTIGATOR(S): Raymond B. Wels	s. M.D. Chief Oncology Medical
FACILITY: WRANC DEPT/SVC: HE	MATOLOGY Oncology - Dept. Of Med.
ACCUMULATIVE MEDICASE COST: ACCUMULATIVE CONTR	ACCUMULATIVE SUPPLY COST:
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2.5 1983
STUDY OBJECTIVE: Evaluate efficacy of Clot patients who fail Clotrimazole prophyla	rimazole RX of Oral Candidiasis in
TECHNICAL APPROACH: Clotrimazole troches 10	
PROSRESS DURING FY-82:	ered in FY 81 .No patients entered
for 82	area in it or two barrenes entered
Humaek of Subjects Studied:	
	BEFORE COMPLETION OF STUDY: 50
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTIC NONE	IPATING IN PROJECT(IF NONE SO STATE):
Conclusions: Too few patients entered to	date to evaluate.
PUBLICATIONS OR ABSTRACTS, FY-82:	
None	

DATE: 10/2/82 N	lork Unit No.:	1696	STATUS	: INTERIM	FINAL X
STARTING DATE:	8/80	DATE	OF COMPLET	ION: 10	/85
Kay Words: Fertili	ty and Sexu	al Function S	tudy		
Time of Project: Win men with non-land normal health	ymphomatus	: Evaluation of malignancies	of Ferti.	lity and Sec lignant chr	xual function onic Illness
PRINCIPAL INVESTIGAT	oa(s): Ray	mond B. Paiss	M.D.		
ASSOCIATE INVESTIGAT	<u>σ</u> ε(s):				*
FACILITY: HRAYC		DEPT/Svc:Hema	tology/0	ncology - D	ept. Of Med.
ACCUMULATIVE MEDICASS	Cost: Ac	CUMPLATIVE CONTRAC	т Созт:	ACCUMULATIVE OO	SUPPLY COST:
FY-83 i EDCASE: Co	NTRACT COST:	SUPPLY COST:	DATE OF ANMUAL	COMMITTEE APP PROGRESS REPOR	ROVAL 0F FEB 2 5 198
TECHNICAL APPROACH: PROGRESS DURING FY-8 entered on this s	Semen analy 2: Study wa	sis prior to F	. No pa	tients were	
MUMBER OF SUBJECTS ST	TUDIED:	· · · · · · · · · · · · · · · · · · ·			
FY-82 <u>: 0</u>	TOTAL (TO	DATE): 0	Befor	RE COMPLETION	OF STUDY: Closed
SERIOUS/UNEXPECTED S	IDE EFFECTS IN	SUBJECTS PARTICIP	ATING IN PI	ROJECT(IF HONE	SO STATE):
CONCLUSIONS:					
None					
	,				
PUBLICATIONS OR ABSTR	RACTS. FY-82:				
MANTE					

2	.	[C				
DATE: 10/2/82 HORK UNIT		STATUS: INTERIM & FIRM				
STARTING DATE: 11/1/8] DATE OF COMPLETION:						
KEY WORDS: Hamolytic And	mia in Runners.					
Title of Project: WRAMC: # 1 and after a Marathon R	697 - the Mechanism	of Hemolytic Anemia before				
PRINCIPAL INVESTIGATOR(S):	Louis F. Diehl, M.D.					
ASSOCIATE INVESTIGATOR(S):	Ray mond B. Weiss, N	M.D. Chief Of Medical Oncology.				
FACILITY: WRANC	DEPT/SVC: Homato	logy/ Oncology - Rept.Of Med.				
ACCUMILATIVE (EDCASE COST:	ACCUMULATIVE CONTRACT C	OST: ACCUMULATIVE SUPPLY COST:				
FY-83 PEDCASE: CONTRACT COS	ST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983				
STUDY OBJECTIVE: this study hematocrit seen in	dy will determone the long distance runner	ne presence, degree and etiology	of the			
		anemia will be determined by me ree hemoglobin in long distance				
PROSESS DURING FY-82: or This study was complete	admormal proteing.	rubjects.	for missing			
Mursen of Subjects Studied:						
FY-82: 8 TOTAL	(TO DATE): 8	BEFORE COMPLETION OF STUDY: 15				
SERIOUS/UNEWECTED SIDE EFFECT	S IN SUBJECTS PARTICIPATIO	NG IN PROJECT(IF NONE SO STATE):				
CONCLUSIONS:						
• •						
PUBLICATIONS OR ABSTRACTS, FY-	82:					

DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL SUBJECT

HSHL-MH

Reply to reviewer of Clinical Investigation Service

Annual Report

TO C, Clin Invest Svc

FROMC, Hem-Onc Svc

10 Dec 1982

· CMT I

1. Maj Rinke requested to know why we have not closed the study after the completion of 8 subjects (WRAMC # 1697 - Hemolytic Anemia in Marathon Runners) The reason the study has remained open is related to the findings in the first eight subjects. It was found that there is a decrease in band 4.1 of the RBC membrane. Since we are investigating the cause of RBC destruction and since this band has been implicated in RBC membrane stability, it is correl ated. We are now investigating the reproducibility of this phenomen in the test tube. Because the laboratory portion of the study is still ongoing, we have elected to continue the study.

Louis F. Diehl, MD

MAJ, MC

Hematology-Oncology Service

DATE: 10/2/82 HORK UNIT N	o.: 1699	STATUS:	INTERIM	X FINAL	
STARTING DATE: 9/80	DATE OF	COMPLETI	ON:		~
KEY VORDS: Delta- 9- Tetra	hydrocannabinol :	for haus	ea and vo	miting by	antineoplastic
TITLE CF PROJECT: WEAMC: # 80 and Vomiting induced by A				rocannabino	ol for Nausea
	James Wilson, MAJ				
PRINCIPAL INVESTIGATOR(S):					
	aymond B.Weiss, M.				
FACILITY: VRANC	DEPT/SVC: Hemat				
ACCUMULATIVE MEDICASE COST: 00	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATI	ve Supply Cos	iT:
FY-83 IFEDCASE: CONTRACT COS	T: Supply Cost:	DATE OF ANNUAL P	COMMITTEE A ROGRESS REP	PPROVAL OF PORT FEB 2.5	<u>1983</u>
STUDY OBJECTIVE To evaluate induced by antineoplastic TECHNICAL APPROACH: Administration	chemotherapy.	sules o	f Delte-9	9 - Tetrahy	rdrocannabánol
PROSESS DURING FY-82: Drugh notobserwation). All data not	t effective clinnic	ally in	any pati	lents to da	
Humber of Subjects Studied:					
FY-82: 2 TOTAL	(TO DATE): 2	Befor	E COMPLETIO	оя оғ Study <u>: 6</u>	pen study
SERIOUS/UNEXPECTED SIDE EFFECT NONE	s in Subjects Participa:	ing in Pa	OJECT(IF NO	ONE SO STATE):	
Conclusions: Too few patie low to acheive desired and	ents entered to date immetic effects.	e. Oral	dose in	protocol m	may be too
PUBLICATIONS OR ABSTRACTS, FY-	82:				Militaria de la composição de la composi

	DATE: 10-2-82 NORK UNIT No.: 1600-81	STATUS: INTERIM X FIRM
	STARTING DATE: 1/81 DATE OF	COMPLETION:
	KEY LORDS: Adjuvant Chemotherapy -Head ar	d Neck
Ra	TITLE CF PROJECT: WRAMC # 8102 - Adjuyant chediation for Stage 111 and IV head and Neck	motherapy following Surgery and /or
	PRINCIPAL INVESTIGATOR(S): David J. Perry, N	I.D.
	Associate Investigator(s): Raymond B. Weiss	, M.D. Chief Medical Oncology
	FACILITY: WRATE DEPT/SVC: Hema	Ology/ Oncology- Dept. Of Med.
	ACCUMULATIVE MEDICASE COST: ACCUMULATIVE CONTRACT 00	
	FY-83 PETCASE: CONTRACT COST: Supply Cost:	DATE OF COMMITTEE APPROVATED 2 5 1983
60: su	STUDY OBJECTIVE: Too evaluate activity of conad and Neck Cancer. To define eligibility iteria in patients with Stage III and IV As TECHNICAL APPROACH: Vinblastine 4.0mg/m2 IV omg/m2 IV day 8 g2ldays x 4 course 1 month argery and / or radiation. PROGRESS DURING FY-82: If in complete remission mbination Chemo. (Velban, Bleo, And Cis-Pi	toxicity, response and resectability and and Neck Cancer. lay 1, Bleomycin 15uim day 1, Cisplatin after achieving complete remission from an following surgery and radiation,
	HUMBER OF SUBJECTS STUDIED:	
	FY-82: 1 TOTAL (TO DATE): 1	BEFORE COMPLETION OF STUDY: closed
	SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPAT NOne	ING IN PROJECT(IF NONE SO STATE):
•	CONCLUSIONS: Lentry in 11 months. Study is	closed due to poor accural.
•	PUBLICATIONS OR ABSTRACTS, FY-82:	

DATE: 10-2-82 WO	dek Unit No.: 1	1601-81 Date o	STATUS COMPLET	: INTERIM X	FINAL	
	otherapy Squ	amous Cell Car			Neck	•
Title of Project: WR. Subsequent Adjuvar of the Head and No.	AMC # 8101 -	Induction Che	mothera	py, Surgery	, Radiation	and noma
PRINCIPAL INVESTIGATE	ox(s): David	Perry, M.D.				
ASSOCIATE INVESTIGATO	R(s): Raymo	ond R. Weiss, N	I.D. Ch	lef, Oncolog	y Service	•
FACILITY: WRANC		DEPT/SVC: Homa	ology/	Oncology- D	ept. Of Med.	•
Accumulative PEDCASE 00	Cost: Acc	UNULATIVE CONTRACT QQ	Созт:	ACCUMULATIVE OO	SUPPLY COST:	•
	NTRACT COST:	SUPPLY COST:	DATE OF ANNUAL	COMMITTEE APPRIPAGES REPORT	OVAL OF FEB 2 5 1983	· !
STUDY OBJECTIVE: To unresectable or adpose and resectable TECHNICAL APPROACH: ed by surgery or reserved and Cis-PLAT quantum PROSRESS DURING FY-82 5/6 have responded	vanced head ility crite Medium dose adiation at 21 days for 2: 7 patient d to therapy	and neck canceria for patient MTX and 5u into week 8- 4 wks 4 cycles. Ls were entered	er. To describe the second sec	Stage 111 as Stage	oflity toxic nd IV Wesd & lete respons n chemothera mphoma on fi	fty,res- Neck Cance: e follow- py(Velban, nal path
Humber of Subjects St						
FY-82 <u>: 3</u>	TOTAL (TO	DATE): 7	Befor	SE COMPLETION OF	F STUDY: 30	
SERIOUS/UNEXPECTED SI	DE EFFECTS IN	SUBJECTS PARTICIPAT	Trig in Pi	ROJECT(IF HONE	SO STATE):	•
CONCLUSIONS:						
Only Make conclusion	5 patinets in as yet.	rom which to g	enera te	data. Not e	enough infor	mation to
PUBLICATIONS OR ABSTR	ACTS, FY-82:					•

DATE: 10/2/82 HORK WHIT	No.: 1602-81	STATUS: INTERIM	x FINAL
STARTING DATE: July 1981	L DATE OF	COMPLETION: June	1984
KEY HORDS: Bone Marrow	Granulocytes pisord	ers	
TITLE OF PROJECT: WRAMC: R			
"C-Glusocamine in orma with primary and second			th patients sera
	Howard Terebelo, M		
ASSOCIATE INVESTIGATOR(S):		· 	
FACILITY: HRANC	DEPT/Svc: Hemat	ology/ Oncology -	Dept. Of Med.
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT	COST: ACCUMULATION	VE SUPPLY COST:
00	00		0
FY-83 i*EDCASE: CONTRACT CO	ST: SUPPLY COST:	DATE OF COMMITTEE ANNUAL PROGRESS REPO	PROVAL OF PRT FEB 2.5 1993
ponsible for the regular marrow granulocyte mat TECHNICAL APPROACH: [react:	iration in :primary ive disorders.)	is. 2. to study t Sone marrow disc	he rate of Bone rders and sec ondary
Serum will be collected chemical characteristic	s. innibition of G.	Lycosylation. Sub	M maturation, bio- stances to be analyzed
Progress Busing FY-82: [will:	l be inhibitors and	stimulators.	-
we are nearing the end of granulocyte proliferation	of this study as we on with inflammator	have identified serum confirmed	a repetitive pattern of by HPLC analysis.
HUMBER OF SUBJECTS STUDIED:		· · · · · · · · · · · · · · · · · · ·	
FY-82: 10 TOTAL	. (TO DATE): 60.	BEFORE COMPLETION	0.5 STUDY: 60
Serious/Unexpected Side Effect NONE	'S IN SUBJECTS PARTICIPAT	ING IN PROJECT(IF NON	E SO STATE):
CONCLUSIONS:Serum from patincreases"C-Glusocamine	ients with inflamma	tory conditions	(Sepsis) dramatically

increases C-Glusocamine incorporated in immature granulocytes. This rate of incorporation corresponds with the granulocyte turnover and decreases over a period of 72 hours.

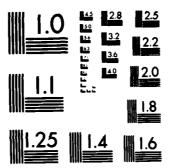
PUBLICATIONS OR ABSTRACTS. FY-82:

[♦] Terebelo, H, Evans, W.H., Effecto of normal and inflammatory Serum on "C- Glusocamine and 3 N-Thymione incorporation onto normal human granulocytes in-Vitro. Blood; Vol. 58, No. 5, Supplement 1: Page 116q, Abstract # 376.

[@] Manuscript in preparation.

DATE: 10/2/82 HORK UNIT N	o.: 1603-81	STATUS: INTERIM X	FIRM
STARTING DATE: 30 june 8	BATE OF	COMPLETION:	
KEY KORDS: Delta-9-Tetra	hydrocannahinol pla	sma levels and Phar	racokinetics.
TITLE OF PROJECT: WRAMC :# 8	Bio4- Delta-9-tetra Pharmacokinet		asma Levels and
PRINCIPAL INVESTIGATOR(S):	James p. Wilson, MA		
ASSOCIATE INVESTIGATOR(S):	Raymond B. Weiss, M	.D. Chief Medical	Oncology Ser.
FACILITY: VRAYC	DEF:/Svc: Hemato	logy/,Oncology =De	pt. Cf Med.
ACCUMILATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT C	COST: ACCUMPLATIVE S	UPPLY COST:
FY-83 PECCASE: CONTRACT COS	ST: SUPPLY COST:	DATE OF COMMITTEE APPRO ANNUAL PROGRESS REPORT	VAL OF FEB 2.5 1983
STUDY USJECTIVE: To determ	mine if a antinausea directly related to		ct of Delta-9-
A	assay by radioimmun		
PROGRESS DURING FY-82: Two	patients entered o	n study.	
HUMBER OF SUBJECTS STUDIED:			
FY-82: ² Total	(TO DATE): 2	BEFORE COMPLETION OF	STUDY: 24
SERIOUS/UNEXPECTED SIDE EFFECT NONE	'S IN SUBJECTS PARTICIPATI	NG IN PROJECT (IF NONE S	O STATE):
CONCLUSIONS: Additional	l patients needed fo	r study.	
			-
PUBLICATIONS OR ABSTRACTS. FY-	·82:		
NONE			

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UN	CLASSIFIED							F	/G 6/5	N		
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		_										
												END
												DATE FILMED
												OTIC



MICROCOPY RESOLUTION TEST CHART
NATIONAL BUREAU OF STANDARDS-1963-A

	× thar to. 1604-81	Sharus: Interin x Fire.	
STATETHE DATE: 80		BATE OF COMPLETION: 6-83	
Key Voras: Adenoca	rcinoma - Undifferent	iated Ca.	
	MC # 8103 - Pilot Stu tiated Carcinoma of U	ndy Of VAR-6 Chemotherapy of Adenocarcinon Unknown Primary.	18
FRINCIPAL PHYSRIBATE	OR(5): Bruce Booth, M.	.D.	
Associate limestigate	ca(s): Raymond B. Weis	ss, M.D.	
FACILITY: HEARC	DEPT/Svc: 1	Hamatalogy/ Oncology -Dept.Of Med.	
Accumulative PEDCASE Q	Cost: Accumplative Com	NTRACT COST: ACCUMULATIVE SUPPLY COST: O	
FY-85 FEDURE: Co.	SUPPLY COST:	DATE OF COMMITTEE PEPROVAL OF PROGRESS REPORT FEB 2 5 1983	
STUDY OBJECTIVE: To carcinoma or undi	determine the efficac	cy of VAB-6 in the treatment of Adeno-	
Cisplatin 120-mg/	g/m2 IV day I — Bleor	day 1 — Vinblastine 4mg/m2 IV day 1-mycin 30 mg/m2 IV day 1,20mg/m2 IM Day 26 n entered. 3 have progressed and died	3.
of their disease.	1 pt. just entered.	m entered. 3 mave progressed and dred	
Norwith of Subjects St	UD. 60.		
FY-52: 4		BEFORE COMPLETION OF SHIDY: 20	
Sericus/Unexercited Si		THE MATERIAL OF PROJECT (IF HOME SO STATE):	
Commusions: Data to	oo sparse at this time	e.	
PUBLICATIONS OR ABSTR	ncts, FY-82:		

DATE: 10-2-82 MORK 1-16T	₩ _{3.1} 1605–82	Status: Interes X Fire.	_
STARTING DATE: 10-81	But	or Commention: 1-83	_
KEY VORDS: AZO - Malter	ant Glioma, Metas	tatic Brain Tumor	_
Title of faculet: wrame # 8 with Malignant Glioma ar	3106- A Collaborati	ive Phase II Study Of AZQ in pa	tients
PRINCIPAL INVESTIGATOR(S): 1	Raymond B. Weiss, N	M.D,	
ASSOCIATE INVESTIGATOR(S): E			
FACILITY: HRANC	DEPT/SVC: Home	stology/Oncology Dept OF Med.	_
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRAC	CT COST: ACCUMULATIVE SUPPLY COST:	
0	0	0	_
FY-83 PEDCASE: CONTRACT CO	DST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 25 196	13
Study Objective: To determ	ine the efficacy of	of AZQ in the treatment of mali	= gnant
Glioma or metastatic Bra	in tumors.		
TECHNICAL APPROACH: AZQ - 2	20mg/m2 in 150-ML c	of NSS over 20 minutes.	-
Paosaass Duaing FY-82: Ente 4 cycles. Has expired.	ered only one patie	ent. Had tumor progression afte	r
HUMBER OF SUBJECTS STUDIED:			
FY-82: 1 Total	L (TO DATE): 1	BEFORE COMPLETION OF STUDY: 15	_
SERIOUS/UNEXPECTED SIDE EFFEC	TS IN SUBJECTS PARTICIPA	ATTING IN PROJECT(IF HONE SO STATE):	_
Conclusions: Data is too	sparse to formulat	te any conclusions.	-
PUBLICATIONS OR ABSTRACTS. FY	-\$2:		_

DATE: 10 2-82 Mask UNIT !	o.: 1606–1 82	STATUS: INTERIM X FIRM	
STARTILIS DATE: 12-81	Page of	Com-LETTION: 12-83	
KEY NORDS: Prothrombotic	State. Adjuvant Cher	notherapy	
TITLE OF PROJECT: WRAMC # 81 In Patients Receiving Ad	.05- Prospective Eva	luation Of Prothrombotic State	1
		(aD.	
ASSOCIATE LINESTIGATOR(S): Ra	ymond B. Weiss, M.D.		
FACILITY: HRAYC	DEPT/Svc: Hematal	ogy/Oncology - Dept. Of Med.	
ACCUMULATIVE PEDCASE COST:		DST: ACCUMULATIVE SUPPLY COST:	
FY-83 PEECASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF INNUAL PROGRESS REPORT FEB 25 1983	
STUDY COLECTIVE: To identif Thrombotic tendency in p	y predosposing predi atients receiving ac	ctive tests for development o	f
TECHNICAL APPROACH Samples o	f plasma will be obt	ained prior to 1st dose of in 3,15,29, and 43 of induction c	duction
PROGRESS DURING FY-82: Plasma	samples have been	collected on 7 entered patient to data analysis has been made	s, to date.
Number of Subjects Studied:			
FY-82: 7 TOTAL	(TO DATE): 7	BEFORE COMPLETION OF STUDY: 20	
SERIOUS/UNEXPECTED SIDE EFFECTS NONE	S III SUBJECTS PARTICIPATII	G IN PROJECT(IR HONE SO STATE):	
NONE Couch 15 tons:	S IN SUBJECTS PARTICIPATH		
NONE Couch 15 tons:			

10-2-82 LV \$555144 RV: 4-		The state of the s	(eq.: 12-82
	ctory Metastatic Car RAMC # 8204- A Colla astatic Carcinoma Re	horative Pha	Se I Trial Of CBDCA in the Conventional Therapy.
former ha arigan	(s): Raymond B. Weis	ss, M.D.	
di ammet <u>a levesticat</u> s	Daniel Tell, M.	_	
		. .	Oncology - Dept.Of Med.
_	1 .		7 (ค.ศ.) การเพราสังสุด, ส จัดและ 0
13 1.100 Cc.	mer Cont. Str. y i	Mr. of	Geographic Property FEB 2.5 1983
patients with me	o'determine toxic tastatic carcinoma r	ity&efficacy efractory to	of CBDCA in treating conventional therapy.
\$ 125 (10 NA)	CBDCA 320 mgm/m2 q 2	28 days.	
disease progress still being trea	ion and expired. 2 html. l patient was to lost of hematology	nave essentia treated 2 x t gical toxicit	
			NE (1) (15) 167 \$ 1.74 10
l patient	experienced severe h	ematological	toxcity.
NONE			

For the second s

10-2-82 | Vas Con Hot 1608-82 | Grown John H. X. Fare 11-81 [19-7] [19-7] [19-7] [19-7] ELLIPTOCYTOSIS WRAMC - Evaluation Of Structural Protein Abnormalities in A Family with Hereditary Elliptocytosis (HE) . Louis F. Diehl ,M.D. Hematalogy/Oncology - Dept.OF Med. O TOTAL CONTROL OF THE CONTROL OF TH 0. 0. (Carrier Court Survival and Carrier Court Survival and Carrier Court Survival to the control of the control of the first section of the control To evaluate four areas of RBC structural protein abnormalities in the Pre and post slenectomy situation. Obtain blood by the standard venipuncture, separate whole blood into cellular fractions and do specific tests. on RBC's. Non-managements from Company of the Aquired all techniques to perform study. 3 × 74:51 1 Family NONE

The tip control to the same that the same th

NONE

over last 12 months.

We will be able to utilize laboratory techniques that we perfected

	1982		Section 1	. 6-83	-
	eukemia, DNA Sy	nthesis			
Kinetics, A Co	GL-13-BC -Le omparative Study	.Of Cytotoxic	lture 3H-TDR in Drugs On DNA Sy	ncorporation and ynthesis and Cel	Growt 1 Grow
	Howa:				
			•₩• . "		
	4 (1)	He.	matalogy/Oncolo	ogy- Dept. Of Me	 d•
		Sign of the state		5	•
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				0	1983
				حجاد هاده د حجاد المحاديق يوس إلى الإدراد ا	
· · · · · · · · · · · · · · · · · · ·	To determine for human CML t	ine if the GL-		is an effective	
· · · · · · · · · · · · · · · · · · ·	for human CML to	ine if the GL- clast crisis.	L3-BC Leukemia	حجاد هاده د حجاد المحاديق يوس إلى الإدراد ا	To de secondo
· · · · · · · · · · · · · · · · · · ·	for human CML to	ine if the GL- clast crisis.	L3-BC Leukemia	is an effective	To de secondo
· · · · · · · · · · · · · · · · · · ·	To determine for human CML to See abstitute Haye fire	ine if the GL- clast crisis.	L3-BC Leukemia	is an effective	data.

Blood Supplement NOV. 1982

10-2-82 | 1 15 Cott H. | 1610-82 | Compt. foresta | X | 1 10-2 4-82 (*** 6.8 million 4-83 Droperidol, HPLC Method WRAMC # 8206 - The Bevelopement of a High Pressure Liquid Chromatagraphic (HPLC) Method to Assay Droperidol. James P. Wilson, Pharmacist - Maj. MC Hematology/Oncology- Dept.Of Med. CONTRACTOR OF THE STATE OF THE STATE OF THE STATE OF THE That of from a first To develop an assay for Droperidol Modify a currently available assay for Haldol and make it applicable for Droperidol. NONE NONE

و الجهر الدول والإستان المستقدم المستقد المست

	4-82	<u>. </u>	
-	Droperidal		
- -	WRAMC # 8209 - Dete Infusion Solutions	rmination Of The Stability Of Droper	rido
ntravenous	Infusion Solutions	عدي معدد المعاد المالية	
٠,	James P. W	ilson, Pharmacist.MAJ. MC	
	, the sin (a):		
•		Hematalogy/Oncology - Dept.Of 1	Med
• •		the state of the s	• • • •
	QU.	1 (1)	
	CE CONTACT CONTENT DO NY	the state of the s	
1 12 1	sati disensi Albania di Sati d	FEB 25	198
Q	To study the rate	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V £
Q	To study the rate	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V £
Q oility of I	Use the HPLC assay	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V £
Q	Use the HPLC assay Droperidol in IV fields	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V £
0 111ty of 1	Use the HPLC assay	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V f
Q	Use the HPLC assay Droperidol in IV fields	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V f
0 111ty of 1	Use the HPLC assay Droperidol in IV fields	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V f
Q:ility of 1	Use the HPLC assay Droperidol in IV fields	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V f
0 111ty of 1	Use the HPLC assay Properidol in IV fields	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V f
Quility of 1	Use the HPLC assay Properidol in IV fields	of decay of Droperidol in various I developed in WRAMC # 8206 and deter	V f

Application of the second of t

DATE: 10-2-82	Mass that the	1612-82	brager	e foreign X foreign
Seasting Dance	3-82	Pai	<u>; e (om+c)</u>	TOTAL
Key Horus: THO	C - Chemother	apy , Nausea	and Vomit	ing
Time of Project:	WRAMC # 8201	- the Use of	Delta-9-T	erra-Hydrocannobinol (TMC)
Personal Invasio	Mater(s): Ja	mes P. Wilson	n, Pharmac	ist. D.
ASSOCIATE INVESTIG	ATOR(S):		^_,·	
FACILITY: NEANC		DEPT/Suc: H	ematology/	Oncology -Dept. Of Med.
Accumulative PERCA	SE Cost: Ac	CUMULATIVE CONTE	LACT COST:	ACCUMULATINE SUPPLY COSTS
FY-83 NECCASE:		Supply Coon:		Constitute Approve Ca Progress Report FEB 2.5 1983
Steam Osutorive: in Cancer chem	To determine	the efficac		as an antiemetic for use
therapy -every	THC 10mg/m2 4 to 6 hours	P 0 4 to 6 h for duratio	ours prion	to adminstration of Chemo- otherapy and for 12 hours
Regards Busy of	-32: Only 1 p	atient has b	een entere	d.
Harest of Suggeors	Stocker:			
FY-82: 1	TOTAL (TO	DATE): 1	Befo	RE COMPLETION OF STUDY: 15
Serious/Unexpected	Side Refects in	STBUECTS PARTIC	αρωτικό το Ε	MONICT(IF NOWE SO STATE):
Conclusions.	MC experience	thus far to	oo limited	to formulate any
Publications on As	STRACTS, FY-82:			

DATE:10-2-82	HORK LINET IN	D.: 1613 -82	STATUS	: INTERIM	_X_	FINAL
STARTILE DATE: 4-82 DATE OF COMPLETION:						
KEY VORDS: Recur	rrent Of Me	tastatic Squamous	Cell C	arcinoma ·	-Head	and Neck
		205 - Master Secti Cell Carcinoma fo				es For Recurrent
PRINCIPAL INVESTIG	GATOR(S): Dav	rid J. Perry, M.D.	 			
ASSOCIATE INVESTI	GATOR(S):					
FACILITY: WRANC		DEPT/SVC: Home	talogy/	Oncology-	Dpet	Of Med
ACCUMULATIVE PEDC	ASE Cost:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATI Q	ive Su	PPLY COST:
FY-83 I'EDUSE:	CONTRACT COS	T: SUPPLY COST:	DATE OF ANNUAL	COMITTEE P PROGRESS REP	PPROV	al Of FR 25 1983
STUDY USJECTIVE: to outline procedure for Phase II studies to screen single agents or combination of agents for significant activity in recurrent or metastatic Head and Neck Cancer. TECHNICAL APPROACH: Bisantrene 260 mg/m2/ IV q 21 days.						
PROGRESS DURING F	1-02: 1 pat:	ient has been ente	ered to	date		
Humser of Susuact	s Swotes:					
FY-82: 1		(TO DATE): 1				
Serious/Unexpected		S IN SUBJECTS PARTICIPA	TIMG IN P	ROJECT(IF NO	OR BIK	STATE):
CONCLUSIONS:	NONE				, , , , , , , , , , , , , , , , , , ,	
PUBLICATIONS OR A	BSTRACTS, FY-	32:				

10-2-82 Ves that the 1614-82 10-84 for the first time 10-84 Fertility, Testicular Cancer

WRAMC # 8207 - Fertility In Men Who Received VAB -III Chemotherapy For Testicular Cancer. David J. Perry, M.D. Hematslogy/Oncology - Dept.of Med. To determine whether fertility has been preserved after treatment with an intensive regimen of chemotherapy drugs. Mailing a questiona-ire and consent form to patients treated with VABIII . Data from questionaire will then be collected, analyzed and prepared for publication. As of this report , protocol has not been approved and therefore has not been implemented. 173 07 1,101 NONE NONE

The second of th

DATE: 10-2-82 Mask GHET No	: 1615–82	Status: Interim X F	(1:5)_
STARTING PAIR 82	Date ce	Commercian: 7-84	
KEY KORDS: Lymphoma, Poor I	Histology		·
Time of Project: WRAMC # 820 Of Relasped , Poor Histor	08 - Combination C	hemotherapy (VAB) in	the Treatments
FRINCIPAL INVESTIGATOR(S): H.	Grant Taylor , M.	D	
ASSOCIATE LINESTIGATOR(S): Rays	mond B. Weiss, M.D	Dayid J. Perry M	.D.
		alogy/Oncology - Dept	
ACCUMULATIVE PEDCASE COST:			
		<u> </u>	
FY-85 MEDCASE: CONTRACT COST	: Supery Cost:	DATE OF COUNTYIES PAPROVAL PROGRESS REPORT	0= EB 2 5 1983
Non-Horigkins Lymphoma treviously treated patients TECHNICAL ASSENDACH: cytoxan (Bleomycin 30U IV day 1, Cisplatin 120mg/m2 IV day PROGRESS DURING FY-82: No par	eated with VAB. 2. 600 mg/m2 IV day 1 20 U/M2 IV day 1-3 y 4.	: Vinblastine 4 mg/m ,Actinomycin D 1 mg/m	of VAB in pre- 2 IV day 1:
Marsex of Susucors Studied:			
FY-82: 0 TOTAL	(TO DATE): 0	BEFORE COMPLETION OF ST	יכע: 14
Serious/Unexpected Side Effects NONE	IN SUBJECTS PARTICIPAT	HIG IN PROJECT(IF HONE SO O	TATE):
Conclusions:			
Too Soon			
TV CV			-
FUSLICATIONS OF ASSTRACTS. FY-SI	4:		

DATE 26 Jan 83 Hogy Cutt 19	o.: 1700	STATUS: INTERIM X FIRM				
STARTIES DATE: 15 June 19	180 DATE OF	CONFLETION: Dec 1983				
KEY KERS: Apnea, Hypoth	yroid					
TITLE CF PROJECT: Sleep Apr	nea in Hypothyroid	Patients				
PRINCIPAL INVESTIGATOR(S): KI	LISHNAN R. RAJAGOPA	L. MAJOR, MC MAJ, MC, Claude J. rellis, LTC, MC				
ASSOCIATE INVESTIGATOR(S): KE	enneth D. Burman, L.	TC, MC, Bahman Jabbari, LTC, MC				
FACILITY: KRAIC	DEPT/SVC: Med	dicine/Pulmonary				
ACCUPARATIVE PEDCASE COST:	ACCUPALATIVE CONTRACT (COST: ACCUMULATIVE SUPPLY COST:				
FY-83 PEDCASE: CONTRACT COS	T: Supply Cost:	DATE OF COMMETTEE APPROVAL OF 2 5 1983				
	nstrate and better of the chyroid patients.	define period of apnea during sleep				
monitore	ed during sleep and	aphic techniques patients will be the records analyzed for the e of appea.				
PROSESS DURING FY-82: Three additional patients with hypothyroidism have been studied and apneas during sleep noted in this group. Because of the difficulty in obtaining patients with hypothyroidism without treatment it is anticipated that this project						
Mursex of Susuects Studied: Wi	ill be combieted in	cooperation with another institution. (belo				
FY-82: TOTAL	(TO DATE):	BEFORE COMPLETION OF STUDY: 10-15				
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NOTE SO STATE):						
NONE	* >					
Coxorusions: Satisfactory	progress.					

Progress During FY-82: (continued) Patients with hypothyroidism and apnea have been identified at the University of Colorado, Denver, and it is proposed that patients from both Medical Centers be reported simultaneously in one publication. Dr. Clifford W. Zwillich has agreed to a collaborative publication.

None

PUBLICATIONS OR ABSTRACTS. FY-82:

					•
DATE: 26 Jan 83 HOSK WIT !	o.: 1701	STATUS	i Interio X	Fire	•
STARTING DATE: December 19	80 DATE O	F COYPLET	10:1: Decembe	r 1983	
KEY KERDS: Medroxy Proge	sterone Acetate, A	pnea			_
TITLE OF PROJECT: Medroxy P	rogesterone Acetat	e, (MPA) in the Slee	p Apnea Syn	drome (SAS)
	•	•			
	. •				•
PRINCIPAL INVESTIGATOR(S): Kr	ishnan R. Rajagopa hman Jabbari, LTC,	1, MAJ, ⋅MC, CL	<u>MC</u> aude J. Telli	s. I.TC. MC	•
ASSOCIATE INVESTIGATOR(S): Ke	ith K. Hunt. jr.	COL, MC			-
FACILITY: KRAYC	DEPT/SVC: Me	dicine/	Pulmonary		_
ACCUPARATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Созт:	ACCUMULATIVE	SUPPLY COST:	:
FY-83 PEDCASE: CONTRACT COS		KUNUAL	Committee Norm Progress Report	FEB 2 5 198	
STUDY OBJECTIVE: To determing April	ne the efficacy of rome. Changes in mproved chemorespo	Medrox frequen nsivene	y Progesteron cy and durati ss as a possi	e Acetate in on of apneional of	the Sleep episodes action
TECHNICAL APPROACH: Nocturna be performed prior to, during	l polysomnography,	hyperc	apnic and loa	ding respons	ses will
medroxy progesterone acetate.	·				
PROSERS DURING FY-82: Three	additional patien	ts were	studied and	the necessar	y data
btained. Excellent sleep re- well tolerated. The large am	cordings have been	obtain	ed and tests	of respirate	ory control
Hurser of Subjects Studied:	·	nas pee	n accumulated	CHOS LAL I	how (below)
FY-82: TOTAL	(TO DATE):	Befo	RE COMPLETION OF	: Sтиру <u>:</u> 15-2	<u>!</u> 0
Serious/Wexpected Side Effects no patient in this study	S IN SUBJECTS PARTICIPA has had any side	TINS IN Peffects	ROJECT(IF HONE !	SO STATE):	•
CowcLusions: Excellent prop	ress has been ach	ieved a	nd the study	is near comp	letion.

PUBLICATIONS OR ASSTRACTS. FY-82: RAJAGOPAL, KR, ABBRECHT, PH, McCUMBER, TR, HUNT, KK: Medroxy progesterone acetate in Obstructive Sleep Apnea. Amer Rev Respir Dis 1982, 125(4):128. (2) ABBRECHT, PH, RAJAGOPAL, KR: Determination of Inspiratory flow resistive load dependent respiratory drive in normal and sleep apneic subjects. Federation Proceedings 1982, 41:1103. (3) RAJAGOPAL, KR, ABBRECHT, PH, TELLIS, CJ: Control of breathing in obstructive sleep apnea. Submitted (4) ABBRECHT, PH, RAJAGOPAL KR, BRYANT, HJ: Respiratory drive components in flow resistive loading for normal and sleep apneic men. Submitted

The tremendous amount of data that has been obtained has to be critically analyzed

and is this is being done with computer help at the medical school.

Progress During FY-82: (continued) being analyzed with computer programming available at the Uniformed Services Medical School.

DATE: 27 Jan 83 LOSK LINET N	o.: 1702	STATUS:	INTERIM X	Free
STARTING DATE: October 19	81 DATE C	F COMPLETION	: Decem	ber 1984
Key Keys: Control of B	reathing, Dementia			
TITLE CF PROJECT: Ventilato	ry Response to Car	bon Dioxid	le in Pres	enile Dementia
		•		
PRINCIPAL INVESTIGATOR(S): Kr	ishnan R. Rajagopa	1, MAJ. MC	3	
ASSOCIATE INVESTIGATOR(S):	hman Jabbari, LTC,	MC, Keiti	1 K. Hunc,	Jr., COL, MC
FACILITY: KRAYE	DEPT/SVC:	edicine/Pu	ılmonary	•
ACCUPALATIVE NEGRASE COST:	ACCUMBLATIVE CONTRACT	Cost: A	CCUMULATIVE	SUPPLY COST:
FY-83 PEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF CO ANNUAL PRO	MITTEE APPRISES REPORT	Royal 0=2 5 1983
		t load con	mpensation	enile-Peachtia is manifested only
TECHNICAL APPROACH: Ventilatin 10 subjects and compacontrols.	ory and loading reared to results obt	sponses to	hypercap similar te	chniques in volunteer
PROSESS DURING FY-82: After were Patient attention span ha	tested on the vent	ilatory h	ypercapnic	, Ft. Sam, two patients response circuit. ical difficulties (below
HUMBER OF SUBJECTS STUDIED:				
FY-82: TOTAL	(TO DATE):	Before	COMPLETION O	F STUDY: 10
SERIOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPA	ring in Proj	ECT(IF HONE	SO STATE):
Comprusions: It has been d	ifficult to find p	atients th	nat adequa	tely meet the

CONCLUSIONS: It has been difficult to find patients that adequately meet the criteria for the protocol, however, it is anticipated that over a 2 year span the study can be completed.

PUBLICATIONS OR ABSTRACTS, FY-82:

Progress During FY-82: (continued) in performing the test in the group. Subsequently, it was decided to attempt the test only on non psychotic presentle dementia patients. It has been difficult to find such patients, however, it is anticipated that over the span of two years enough patients will be obtained to complete the trial.

	DATE: 27 Jan 83 Hoak Livet	No.: 1703	STATUS: 11	ITERIM X	Fire
	STARTING DATE: July 198	O DATE OF	CONFLETICH:	Decembe	er 1984
	Key licros:				
	Time of Project: Comparis pulmonar	on of daily vs alter y sarcoidosis.	nate day F	rednisone	therapy in
•	B PRINCIPAL INVESTIGATOR(S):	. Lynn Feaster, M.D.	MAJ, MC		
	ASSOCIATE INVESTIGATOR(S): L				LTC, MC
	FACILITY: HRAYE	DEPT/Svc: Med	licine/Pul	nonary	
	ACCUPARATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT (Cost: Acc	umulative Su	PPLY COST:
•	FY-83 PEDCASE: CONTRACT CO	-	AMNUAL PROGR		EEB 25 1983
•	as daily	mine if alternate day therapy in the trea	etment of p	pulmonary	sarcoidosis
CXR	TECHNICAL APPROACH: Patient every pulmonary functions and	its with Stage II sar day or alternate day id serum chemistries	therapy	for 6 mont	ly assigne d to hs. Clinical status
•	PROSRESS BURING FY-82: Few a	dditional patients h	nave been	studied.	Patients from other
	ical centers are also be	ing included and hop	pefully the	e project	will be completed
on -	Hurser of Subjects Studied:				
_	FY-82: 10 Total	L (TO DATE): 25			STUDY: 50-100
	SERIOUS/UNEXPECTED SIDE EFFECTED None	TS IN SUBJECTS PARTICIPATI	ing in Projec	T(IF NOVE SO	STATE):
•	CONCLUSIONS: Progress has on time.	been satisfactory and	nd hopeful	ly protoco	T will be completed
	•			•	
_	<u> </u>	···			·
	PUBLICATIONS OR ABSTRACTS. FY	-82:		•	

DATE: 28 Jan 83 YORK LINET N	o.: 1704	STATUS	: Інтенін х Риза	-
STARTING DATE: October 19	BO DATE O	F COYFLET	ici: December 1984	_
Key leas: high freque	ncy ventilation, A	RDS		_
TITLE CF PROJECT: High frequency with respi	ency positive pres ratory failure	sure ve	ntilation (HFPPV) in pat	ients
TRIFELENE INVESTIGATION 131	ames J. Bombenger,			_
ASSOCIATE INVESTIGATOR(S): S.S	. Derderian, MAJ,	MC, Kri	shnan R. Rajagopal, MAJ,	MC
FACILITY: KRAYE	DEPT/Svc: Med	licine/P	ulmonary	_
ACCUPALATIVE PECCASE COST:	ACCUIDATIVE CONTRACT	Cost:	ACCUMULATIVE SUPPLY COST:	
FY-83 PEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF ANNUAL	COMMETTEE APPROVAL OF PROGRESS REPORT FEB 2 5 198	- 3
respirator	y failure who can	ot be s	e life-saving in-patient supported by conventional	l means.
TECHNICAL APPROACH: In patie for fail initiated and physiologic his/her own control and the state of the stat	ents with respirate ure to improve on and hemodynamic re there will be no re	ory tail convent measurem	ure who meet the presettional ventilation HFPPV ments made. Each patien election.	criteria will be t will be
PROSESS DURING FY-82: Because the Unit during this fis available this year an available this year.	of the lack of ectated on patients scal year. It is a verage of 5-10 pat	uipment with re anticipa ients sh	support this protocol espiratory failure in the sted the when equipment hould be studied over a	could not e intensive becomes 6 month period
Hurser of Subjects Studied:				-
FY-82: 0 TOTAL	(TO DATE): 1	Befo	RE CONSLETION OF STUDY: 20	· -
SERIOUS/UNEXPECTED SIDE EFFECT None	S IN SUBJECTS PARTICIPA	TING IN P	ROJECT(IF HOME SO STATE):	-
CONCLUSIONS: Lack of the ne progress on this protocol fully be completed on time	 As the equipment 	support nt becom	t has resulted in inadeq mes available the study	ūate will hope-
PUBLICATIONS OR ASSTRACTS. FY-	S2:			-
Associate Investigat	or(s): (contin	ued)		
Claude J. Te	llis, LTC MC			

DATE: 27 Jan 83	HORK LINET No.:	1705	STATUS: INTE	RIM X	Fire	
STARTILE DATE:	November 1980	DATE OF	COFLETICH:	December	1983	
Key lords: Exerci	se respiratory	control, loaded	i breathing			
TITLE OF PROJECT:	Determinants of	of resistive load	ied breathin	ng		
	·		• .			
PRINCIPAL INVESTI	GATOR(s): Peter	Ḥ. Abbrecht				
ASSOCIATE INVESTOR	CATOR(s): Krishr	nan R. Rajagopal	MAJ, MC			
FACILITY: KRAYE		DEPT/SVC: Med	dicine/Pulmo	nary	•	
ACCUMULATIVE PECC	ASE COST: ACC	CUMPLATIVE CONTRACT (OST: ACCUM	PLATIVE SUP	PLY COST:	
FY-83 PEDCASE:	CONTRACT COST:	Sugar ve Coom	P C			
7705 72005.			DATE OF COMMIT ANNUAL PROGRES	tee heprova is Report E	LOF EB 25 1983	
STUDY OSJECTIVE:	To define the	mechanisms that	determine,	pe respon	The r	espiratory.
the relationshi patients with c	ps among flow. hrofic obstruc	mechanisms that increase in external resistance and tive pulmonary	respiratory	drive in	normal sub	jects and
		responses during three levels of the addition of				
during loading,	Responses to	threshold loading	ıg.	•	;	•
PROSRESS DURING F	7-82: Four norms	l volunteers had ocol. Each test have been obtaine	e been test run is an	ed sucess extensive	fully usi ng , often 4-5	the day, duration
		nave been obtaine action of data ha				ogress nas
Hursen of Subjects	STUDIED:					
FY-82 <u>:</u> 4	TOTAL (TO	DATE): 4	BEFORE COM	LETION OF S	18 Tudy:	. •
SERIOUS/UNEXPECTED	SIDE EFFECTS IN	SUBJECTS PARTICIPATI	HG IN PROJECT(IF HOME SO	STATE).	
N/a	<u> </u>		•	•		. ,
Conclusions: With	continued pro he expected da	gress it is ant: ite.	cipated tha	it this st	ady will b e	: completed
•			•			
		•	•	•	•	•
<u>.</u>	•			· 		**************************************
PUBLICATIONS OR AS	BSTRACTS. FY-82:					•

1707 Date: 27 Jan 83 YORK LINET NO.: STATUS: INTERIM FI 30 June 1984 May 1981 STARTILLE DATE: DATE OF COMPLETICH: Key kees: pulmonary fibrosis, nocturnal desaturation TITLE CF PROJECT: Relationship between respiratory control mechanisms and nocturnal desaturation in diffuse pulmonary fibrosis PRINCIPAL INVESTIGATOR(S): Krishnan R. Rajagopal, MAJ, MC Warren I. Tamamoto, CPT, MC Keith K. Hunt, Jr., COL, MC 34. ASSOCIATE INVESTIGATOR(S): Medicine/Pulmonary DEPT/Syc: FACILITY: KRAYE ACCUPALATIVE PEDCASE COST: ACCUMULATIVE CONTRACT COST: ACCUMULATIVE SUPPLY COST: FY-83 PECCASE: CONTRACT COST: SUPPLY COST: Date of Committee Peproval OF ANNUAL PROGRESS REPORT FEB 2 5 1983 To evaluate the relationship between respiratory source mechanisms assessed in the awake state and nocturnal desaturation in a well STUDY OSJECTIVE: defined group with pulmonary fibrosis TECHNICAL REPROACH: To study subjects with pulmonary fibrosis with standard nocturnal polysommographic techniques and identify the frequency and severity of desaturation. Respiratory control will be assessed by hypercapnix and loading responses and the relationship between nocturnal desaturation and respiratory control will be PROSESS DESCRIPT FY-82. The equipment necessary for the start of this protocol is as yebelow packard system were found to be consistently unsatisfactory. Subsequently a Beckman Dynograph (a multichannel polysomnographic recorder) has been requested. (below) Humber of Subjects Studied: 20 Patients FY-82: TOTAL (TO DATE): BEFORE COMPLETION OF STUDY: 20 controls SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NOTE SO STATE): Coxcusions: The capnometer which is initially not available is currently being used

PUBLICATIONS OR ASSTRACTS. FY-82:

Technical Approach: (continued) assessed and compared to data obtained by similar techniques in controls.

in the laboratory. However, a reliable polysomnograph is not available and until such equipment is available this and other related protocols cannot be initiated.

Progress During FY-82: (continued) Progress with this protocol is possible only if the recorder becomes available. Currently in our laboratory a capnometer which is necessary for recording transcutaneous carbon dioxide measurements during sleep is available. The only hold-up is the lack of the polysomonograph.

DATE: 27 Jan 83 HOPE LINET IK	1708	STATUS:	Interin X	Fii:	_	
STARTIES DATE: May 1981	DATE OF	F COYPLETI	য়ে: Decembe	r 1984	_	
Key logs: Respiratory control, palatal myclonus						
TITLE CF PROJECT: Respiratory	y control mechanism	ms in pa	latal myclon	us		
	·	• .		#4	·	
PRINCIPAL INVESTIGATOR(S):	Krishnan R. Rajago	pal, MAJ	, MC		•	
ASSOCIATE INVESTIGATOR(S):	Bahman Jabarri, LT Keith K. Hunt, Jr.	C, MC	iC ;	25.34°	•	
FACILITY: KRA'C	DEPT/SVC:	Medicin	e/Pulmonary	•	•	
ACCUPALATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE S	SUPPLY COST:	2	
FY-83 FEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF ASSESSED F	COMMITTEE PARK PROGRESS REPORT	FEB 2 5 196	<u>-</u>	
STUDY OSJECTIVE: 10 study represented lesions of the bra TECHNICAL APPROACH: VVentila hypercap colunteer subjects using s	tory and respirato nic and loading re	ry drive sponses			• .	
Prosess Due 100 FY-82: One ad	ditional patient w	ith pala	tal myclonus	has been s	Eudied.	
Even though this is an ext It is conceivable that wit	remely rare disord hin the time of th	er we na e protoc	ol the requi	red number	of patients	
Hursen of Subjects Studied: wi	11 be studied.				-	
FY-82: 1 TOTAL	(TO DATE): 4	Befor	SE CONPLETION OF	F Sτυρ <u>γ: ⁶</u>	. <i>•</i> ~	
SERIOUS/UNEXPECTED SIDE EFFECT	'S IN SUBJECTS PARTICIPA	ities in Pi	EDUECT(IF HONE	SO STATE):	- .	
	· / N/A	•				
Conclusions: Satisfactory	progress and the p	rotocol	should be co	mbreced ou	time.	
			•		•	
• . •			•		• .	
					· .	
PUBLICATIONS OR ASSTRACTS. FY-	82:			•	-	

::

DATE: 27 Jan 83 Hope Unit No.: 1709 STATUS: INTERIM اد:: F STARTIES DATE: March 1981 December 1984 DATE OF CONFLETION: KEY KOPOS: lung mechanics, mixed connective tissue disease TITLE CF PROJECT: Lung function in subjects with mixed connective tissue disease Claude J. Tellis, LTC, MC Sarkis S. Derderian, MAJ, MC PRINCIPAL INVESTIGATOR(S): Krishnan R. Rajagopal, MAJ, MC ASSOCIATE INVESTIGATOR(S): FACILITY: HRAYC DEPT/SYC: Medicine/Pulmonary ACCUPARATIVE PEDCASE COST: ACCUMPLATIVE CONTRACT COST: ACCUMULATIVE SUPPLY COST: FY-83 PEDCASE: CONTRACT COST: SUPPLY COST: DATE OF COMMITTEE PEROVAL OF PARISHED PROSPESS REPORT FEB 2 5 1983 Stupy On Ecriva: To evaluate abnormalities and pulmonary functions in untreated and treated patients with mixed connective tissue disease. TECHNICAL APPROACH: To include a history and physical examination and routine and sophisticated tests of pulmonary functions. Such tests would include lung volumes, flo and tests of respiratory mechanics to include compliance. Tests of distributional (below) PROSRESS DURING FY-82: A few subjects with mixed connective tissue disease that have been referred to this service have been studied. Adequate material has been obtained but harepsilonnot bee subject to statistical analysis. Hursen of Subjects Studied: FY-82: TOTAL (TO DATE): 12 BEFORE COMPLETION OF STUDY: SERIOUS/UNEXPECTED SHOE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NOME SO STATE): No major sides effects were noted with this study. Conclusions: Fairly adequate progress has been made with this protocol and because of the

PUBLICATIONS OR ASSTRACTS, FY-82:

Technical Approach: (continued) ventilation including nitrogen washout, and tests of airways resistance and small airways function will also be assessed. Balloon type catheters will be used for measurement of compliance and transdiaphragmatic pressure.

anticipated that the study could be completed on time.

limited number of patients with mixed connective tissue disease that are available for study it has been difficult to increase the number of subjects studied. It is however,

DATE: 27 Jan 83	PORK UNIT NO	. 1710	STATUS	: Interim X	Firm	
STARTILE DATE:	March 198		COFLET			
TITLE OF PROJECT:	Relationsh	thing, nocturnal of ip between respiration in obese subjections.	tory co	ontrol mechani	sms and noc	turnal
PRINCIPAL INVESTI		rren I. Tamamoto,				
ASSOCIATE INVESTI	GATOR(s): Kei	th K. Hunt, Jr., (OL, MC	, Kenneth D. I	durman, LTC,	MC
FACILITY: WRANG		DEPT/SVC:		ne/Pulmonary	· ', •	
Acord ative PEC	ASE Cost:	ACCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE S	UPPLY COST:	
FY-83 FEDCASE:	CONTRACT COST	SUPPLY COST:	DATE OF PANUAL	COMITTEE HAPRO PROGRESS REPORT	FEB 2 5 1985)
TECHNICAL APPROACE techniques will the relationship	rol mechani H: Respirato flow resi be used to between ch	frequency and seve c obese subjects a sms and nocturnal ry control mechan; stive loading resp assess the frequency emical control mechanical ewlett-Packard cap ility of arterial	desatu isms wi conses. ncy and chanism	ration in obes ll be assessed Standard nod severity of r s and frequence with transcu	se pts vs no d using hype tturnal poly nocturnal de ry and sever taneous mon	n-obese contro rcapnic and sommographic saturation. ity of (below)
		ility of arterial he annual report o an major obstacle.	Until	a polysomnogr	aph is avai	lable(below)
Hursen of Suscect	ं स्वाकार या				(2	0 subjects) 0 controls)
FY-82 <u>:</u>	TOTAL	(TO DATE):	Befo	RE COMPLETION OF	Sτυργ: 40	
Serious/Unexpecti N/A	ED SIDE EFFECT	S IN SUBJECTS PARTICIPA	TING IN F	ROJECT(IF HOME S	O STATE):	•
Conclusions: The	study will this labora	begin when multi-	-channe	l recording ca	apabilly is	available
•			•		•	•
•				•	.	
	.				18.5	- ·
PUBLICATIONS OR I	ABSTRACTS. FY-	82: ·.			• '	•

Technical Approach: (continued) nocturnal desaturation episodes will be analyzed using appropriate statistical methods.

Progress During FY-82: (continued) for multichannel recording is available this protocol cannot be initiated.

				
DATE: 27 Jan 83 How Unit No	.: 1711	STATUS: INTERIM		
STARTILE DATE: 29 May 1981		COFCETION.	ecember 1983	
NET /4/33-	chritis, pulmonary		ng	
TITLE OF PROJECT: Pulmonary	Function in Psoriat	ic Arthritis		
		<u>.</u>		
PRINCIPAL INVESTIGATOR(S): B.	Lynn Feaster, MAJ,	MC		
ASSOCIATE INVESTIGATOR(S): Kr	ishnan R. Rajagopal	,MAJ, MC, R. R	askin, MC∷≇	•
FACILITY: KRAYC		icine/Pulmonar		•
ACCUMULATIVE PEDCASE COST:	ACCUMILATIVE CONTRACT	Cost: Accumul	ATIVE SUPPLY COST:	
FY-83 PEDCASE: CONTRACT COS	l		EPORT FEB 2 5 198	
STUDY OSJECTIVE: To determin psoriatic a		•		30
lung com	n complete pulmonar pliance and related riaric arthritis.	ry function tes d measurements	of lung.mechanic	s of patients
PROGRESS DERING FY-82: Equipment have be function has been observed	een studied using	ary has been ob this protocol a	otained. About I and abnormalities	O patients in pulmonary
Hursen of Subjects Studied:		•		•
FY-82: 10 TOTAL	(TO DATE): 10	BEFORE COMPLE	TION OF STUDY: 20	-
SERIOUS/UNEXPECTED SIDE EFFECT	'S IN SUBJECTS PARTICIPA	THIS IN PROJECT (IF	HOWE SO STATE):	•
None	• • • • • • • • • • • • • • • • • • • •		·	-
Corcusions: Adequate prop	gress has been made	•		
•		•		
			:	
				<u> </u>
PUBLICATIONS OR ASSTRACTS. FY	- 8 2:		_ **	

DATE: 10/1/82 HOSK BATT N	o.: 1712	STATUS	: Interior X	Final		
START 1:35 DATE: 1 Jul 82	DATE O	e Corplet	ion: 1 Jul	83		
Key Noes: Somato Sensory Evoked Response-Chronic Pulmonary Disease						
TITLE OF PROJECT: Investigation	TITLE CF PROJECT: Investigation of abnormalities of Somato-Sensory Evoked Responses					
in patients with chronic	pulmonary disease		·			
PRINCIPAL INVESTIGATOR(S):	ı Jabbari, LTC, MC		sh Rajabopal	MAJ, MC		
ASSOCIATE INVESTIGATOR(S): Ca	arl H. Gunderson Co	OL MC				
FACILITY: HRANC Evoked Lat	DEPT/SVC:	Neuro	ogy			
Accumulative PEDCASE Cost:	ACCUHULATIVE CONTRACT	Созт:	ACCUMULATIVE S	SUPPLY COST:		
FY-83 FEBCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF ANNUAL	COMMITTEE APPROPRIES	OVAL 07 FEB 2 5 1983		
pathwasy in CUPU.	nine presence or ab				-	
TECHNICAL APPROACH: Patients with established COPD are tested by the somatosensom and peripheral conduction velocity studies-Peripheral and central conduction velocities are measured.						
PROSERS DURING FY-82: One patient with CPD was tested. The central conduction time was normal. The peripheral sensory conduction was delayed.						
HUMBER OF SUBJECTS STUDIED:				·		
FY-82: 1 TOTAL	(TO DATE): 1	Before	RE COMPLETION OF	STUDY:		
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF HORE SO STATE): None						
Conclusions: This study shall the central s	owed presence of a ensory conduction	was nor	peripheral mal.	neuropathy.	,	
				_		
PUBLICATIONS OR ABSTRACTS. FY-8	2:					
None.						

53

DATE: 11/10/82	Hoek liver lio	: 1803	STATUS	Interin	First X	•
STARTICE DATE:	DAIR: 11/10/02 1-31-31-31-31-31-31-31-31-31-31-31-31-31					
Key Viceos:		TERMINATION OF	PROJECT			
TITLE OF PROJECT:		•				
FAMILY 1	WITH HERED!	TARY MYXO-VASCULA	AR FIBROM	AS		
PRINCIPAL INVESTI	erma(e).	IOHN L PETER	TON WAT	vc (He i	s no longer a	÷ WRAI
ASSOCIATE INVESTI		TOHN I PELEK	MALL.	<u> </u>	7.34	**
FACILITY: KRAYE		DEPT/Svc:	,	ERMATOLOGY	SERVICE.	٠
ACCURATIVE PER		ACCUMALATIVE CONTRA			SUPPLY COST:	
FY-83 PEDCASE:	CONTRACT COS	T: SUPPLY COST:	DATE OF ANNUAL	COMITTEE LANDERS REPORTED	ROVAL OF ET FEB 2.5 1987	
STUDY OBJECTIVE:			• .			•
TECHNICAL APPROA	<u>01</u> :				•	
PROSRESS DURING	<u>FY-82</u> :					•
Hursen of Susjec	TS STUDIED:		• .			•
FY-82: TOTAL (TO DATE): BEFORE COMPLETION OF STUDY:			OF STUDY:	_		
Sentous/Unexpect	ED SIDE EFFECT	'S IN SUBJECTS PARTIC	ipating in P	ROJECT(IF NOW	E SO STATE):	•
Conclusions:						•
•						
	•		•			•

PUBLICATIONS OR ASSTRACTS. FY-82:

DATE: 12 Nov. 82 York Lint N	5.: #1804	STATUS	ं क्षित्रहरूव	अञ्चलक
STARTILE DATE: 1 October 19	82 DATE O	if Conflet	ich: anticipa	ted June'83
KEY VORDS: Intralesional B	leomycin. Wart tre	atment		
TITLE OF PROJECT: Warts, Tr	eatment with Intra	lesiona	l Bleomycin	
		• .		
PRINCIPAL INVESTIGATOR(S): Ch	arles B. Weber, Ma	j. MC		
ASSOCIATE INVESTIGATOR(S): Le	onard Sperling, Co	t. MC	Stacey McM	arlin, Col. MC
FACILITY: KRAYE	•			n. Col.MC/Chief
ACCURALATIVE PERCASE COST:	ACCUMBLATIVE CONTRACT	Cosr:	ACCUMULATIVE	SUPPLY COST:
FY-83 FEDCASE: CONTRACT COS		0.00	COMMITTEE APP	\$0.00
\$0.00 \$0.00		NAME OF	PROGRESS REPORT	FEB 2 5 1983
effective treat TECHNICAL REPROACH: Use pat bleomycin and a PROSRESS DURING FY-82: Code has shown resol	ind test of whethe ment for previousl ient as their own nother wart with d not broken, but in ution, while the o	control iluent. double	by injecting	one wart with
HUMBER OF SUBJECTS STUDIED:				
FY-82: three Total	(TO DATE): three	Befo	RE COMPLETION O	of Study:
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPA	TIPS IN P	ROJECT(IF HONE	SO STATE):
		•	•	Holle
Coxcusions: Preliminary re	sults look promisi	ng.		
			•	
			•	
<u> </u>	1			
PUBLICATIONS OR ASSTRACTS. FY-	82: none			

DATE: Oct 1982 HOPK UNIT I	o.: 1905	STATUS: INTERIM X	Fire			
STARTING DATE: 27 Sep 1977 DATE OF COMPLETION: 1983						
NFY 1212.15:	Key loss: Neisseria gonorrhoeae, local immunity					
TITLE OF PROJECT: Local Imm	une Response to Neis	seria gonorrhoeae	in Humans			
PRINCIPAL INVESTIGATOR(S): EDMUND C. TRAMONT, COL, MC John W. Boslego, MAJ, MC						
ASSOCIATE INVESTIGATOR(S): J	ennie Ciak, GS-12					
FACILITY: HRATE	Depr/Svc: Infec	tious Disease Serv	rice			
ACCUMULATIVE PEDCASE COST:	ACCUMPLATIVE CONTRACT CO	OST: ACCUMULATIVE	SUPPLY COST:			
\$20,000.00	\$1,000.00	\$15,000				
FY-83 i'EDCASE: CONTRACT COS	ST: SUPPLY COST: \$1,000.00	DATE OF COMMITTEE APPR PANUAL PROGRESS REPORT	OVAL 0F FEB 2 5 1983			
STUDY CRITICE: To study the local immune response to mucosal infection with N. gonorrhoeae or to immunization with a gonococcal vaccine.						
TECHNICAL APPROACH: Male and female local secretions are collected following natural infection or immunization. Antibody levels are measured by ELISA or SPRIA. Functional antibodies are measured via the inhibition of attachment ass						
PROSESS DURING FY-82:						
(See attached sheet)						
Number of Sussects Studied: All human subjects immunized under separate protocol						
FY-82: TOTAL (TO DATE): BEFORE COMPLETION OF STUDY:						
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE):						
- NONE .						
CONCLUSIONS: These findings suggest that a gonococcal pilus vaccine may be efficacious in preventing gonorrhea.						
TUBLICATIONS OR ABSTRACTS, FY-	82:					

Progress during FY-82:

- Monoclonal antibodies were raised which are specific against N. gonorrheae pili (the gonococcal vaccine). These antibodies are to be used to study the antigenic heterogeneity of gonococcal pili.
- 2. Local antibodies induced by the gonococcal pilus vaccine were further evaluated and found to bind to heterologous pili. These antibodies also inhibit the binding of homologous and heterologous strains of \underline{N} . gonorrheae to epithelial cells.
- 3. The "functional" antibody which inhibits binding of heterologous strains to human epithelial cells can be absorbed by a single heterologous strain. This suggests there is a common determinant shared by many gonococcal pili which reacts with a functional antibody indiced by a single pilus strain.

DATE: 25 Jan 83 Nosk UNIT No.: 1908	STATUS: INTERIM X FIRM
STARTILLE DATE: 4 April 1978 DATE C	F COMPLETION: 1983
KEY Normaniasis; treatment; penta	valent antimony; Pentostam
TITLE CF PROJECT: Evaluation of sodium stibog	luconate (Pentostam) in the
treatment of cutaneous leishmaniasis.	
PRINCIPAL INVESTIGATOR(S): Charles N. Oster. M	D LTC. MC.
Associate Investigator(s): Pamplin, C., Chulay	D. LTC. MC ielā, C.J., Hendricks, L.D.,
	icine/ Infectious Disease
ACCUMULATIVE PEDCASE COST: ACCUMULATIVE CONTRACT O O	COST: ACCUMULATIVE SUPPLY COST: \$4,000.00
FY-83 PEDCASE: CONTRACT COST: SUPPLY COST: \$2,000.00	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT 26 Jan 1982
STUDY OBJECTIVE: a) To evaluate the efficacy stibofluconate (Pentostam) for the treatm To observe for long term sequelae of leis TECHNICAL APPROACH: Unchanged	y of different regimens of sodium ent of cutaneous leishmaniasis. (b) hmaniasis and its treatment in mil. personne
PROGRESS DURING FY-82:	
Municipal Subjects Studied:	
FY-82: TOTAL (TO DATE):	BEFORE COMPLETION OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPA	TING IN PROJECT(IF HOME SO STATE):
None	
CONCLUSIONS: See inclosed write-up	
•	
D'M	
Publications or Abstracts, FY-82: See inclosed write-up	
see inclosed write-up	

Work Unit #1908

Protocol: Evaluation of Sodium Stibogluconate (Pentostam $^{\rm R}$) in the Treatment of Cutaneous Leishmaniasis.

Investigators:

Charles N. Oster, M.D., LTC, MC Jeffrey D. Chulay, M.D., LTC, MC Jonathan D. Berman, M.D., MAJ, MC W. Ripley Ballou, M.D., MAJ, MC

Since 1978 we have seen 59 patients with cutaneous leishmaniasis. 55 had American cutaneous leishmaniasis: 50 of these acquired their disease in Panama. Among 34 patients with a short period of exposure, the incubation period ranged from 4-81 days. Diagnosis was delayed an average of 90 days after onset, due to a combination of the patients' delays in seeking medical attention (36 days), physicians' delays in suspecting the right diagnosis (38 days) and delays due to difficulties in laboratory comfirmation of this diagnosis (16 days). Fifteen patients had atypical, non-ulcerative lesions that would not have been recognized if leishmanial cultures had not been obtained. Only 30 of 54 patients (56%) were cured with the initial course of sodium stibogluconate. Lesions larger than 2 cm diameter were less likely to respond than smaller lesions (40% vs 89%, P=0.016).

Pharmacokinetic studies of our patients (Pamplin, et al) demonstrated very rapid clearance of sodium stibogluconate. Therefore, when giving this drug on the standard once daily schedule, measurable blood levels are present only for the first 6 hours of each day. On the basis of this data, we speculated that the poor rate of response to treatment was due to the administration schedule. We tested this hypothesis by randomly assigning patients with leishmaniasis to receive sodium stibogluconate by three schedules: A-once daily, B-continuous infusion, and C-eight hourly. All received 10 mg/kg/d, to a maximum daily dose of 600 mg, for 10 days. 36 patients were treated under this protocol. The overall response rate to the first course of therapy was 63%, but was better for schedule A (100%) than B (50%) or C(42%) (P=0.006). Seven additional patients were treated concurrently with the standard, once daily, sodium stibogluconate schedule; only 4(57%) of these responded to the first course.

We are unable to explain the difference in the rates of response between the identical, once-daily schedules, A and standard. Patients with lesions larger than 2 cm diameter were equally distributed between the groups. We have speciated the parasites isolated from 20 of these patients using isoenzyme technics: 9 were L. braziliensis, 7 L. mexicana, 3 L. chaqasi, and 1 unique, as yet unidentified organism. The response to treatment was lower for patients infected with L. braziliensis than with the other species (2 of 9 vs 10 of 11, P=0.003). L. braziliensis lesions were also larger (3.6 \pm 1.4 cm vs 1.7 \pm 1.1, P 0.005). Therefore, it is not clear whether the low response rate of the L. braziliensis lesions is due to their larger size, or to some other property of this species. L. braziliensis patients were equally distributed among the treatment groups; therefore, chance assignment of fewer L. braziliensis patients to group A does not explain its better response rate. Also, clinical treatment failures do not appear to be due to parasitic resistance to sodium stibogluconate (Berman et al).

Our experience with patients with cutaneous leishmaniasis has identified several problems which we will investigate:

1) Diagnosis: The lesions of American cutaneous leishmaniasis often contain few parasites. Consequently, demonstrating the organism by the currently available technics (histopathology and culture) is a laborious, frequently unrewarding task. We will investigate newer technics of hopefully greater sensitivity: monoclonal antibodies, K-DNA probes, and Western blot analysis of antibody response to specific antigens.

2) Treatment: Our overall success rate of 60% with one course of sodium stibogluconate is inadequate. We will investigate whether higher doses of sodium stibogluconate can improve the response. Furthermore, using the technics mentioned above, it may be possible to rapidly identify the infecting species and thus prospectively study the relationship between the species and the response to treatment.

Abstracts and Publications:

- 1. Pamplin CL, Desjardins R, Chulay JD, Tramont EC, Hendricks LD, Canfield CJ. Pharmacokinetics of antimony during sodium stibogluconate therapy for cutaneous leishmaniasis. Presented at the American Society of Clinical Pharmacology and Therapeutics. New Orleans, 1981.
- 2. Berman JD, Chulay JD, Hendricks LD, Oster CN. Susceptibility of clinically sensitive and resistant Leishmania to pentavent antimony in vitro. Am J Trop Med Hyg 1982: 31:495-465.
- 3. Chulay JD, Oster CN, Hendricks LD. American cutaneous leishmaniasis: clinical presentation and problems of management. Manuscript in preparation.
- 4. Oster CN, Chulay JD, Hendricks LD, McGreevy P. Pamplin CL, Tramont EC, Takafugi EJ, Canfield CJ. American cutaneous leishmaniasis: a comparison of three sodium stibogluconate (Pentostam^R) treatment schedules. Manuscript in preparation.

DATE: 7 Oct 82 Mark Burt No.: 1911 STATUS: INTERIM XX FIRM STARTING DATE: 27 Feb 79 DATE OF COMPLETION: Extended KEY ICROS: TITLE OF PROJECT: In Vitro Inhibitory Activity of a Series of 2-Acetylpyridine Thiosemicarbazones Toward Clinically Significant Bacteria PRINCIPAL INVESTIGATOR(S): Arthur S. Dobek, Ph.D. Daniel L. Klayman, Ph.D. J. Bruce McClain, MD, MAJ ASSOCIATE INVESTIGATOR(S): FACILITY: KRAYC DEPT/Syc: Department of Clinical Investigation ACCUMULATIVE PEDCASE COST: ACCUMPLATIVE CONTRACT COST: ACCUMULATIVE SUPPLY COST: .\$381.09 FY-83 PECCASE: CONTRACT COST: DATE OF COMMITTÉE REPROVAL OF 1983 SUPPLY COST: STUDY OBJECTIVE: To determine the in vitro inhibitory activity of a series of 2-acetylpyridine thiosemicarbazones and related compounds toward a collection of clinically significant bacterial organisms. TECHNICAL APPROACH: The minimum inhibitory concentrations (MICs) of the 62 compounds tested have already been reported in the FY 81 annual progress report. PROGRESS DURING FY-82: The serious illness of one coauthor (DLK) has interrupted the completion of a report for publication, specifically that aspect concerning the interpretation and significance of the chemical structures as related to their MICs. In the meantime a request for a time extension of this protocol has been submitted and approved so that the MICs of classes of water-soluble thiosemicarbazones can be determined NUMBER OF SUBJECTS TO BE STUDIED BEFORE COMPLETION OF STUDY: SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT: N/A

CONCLUSIONS: 1. Completion of the report for publication will be accomplished as soon as it is feasible. 2. The water-soluble thiosemicarbazones are being chemically synthesized and will then be tested in vitro.

PUBLICATIONS OR ABSTRACTS, FY-82: Abstract was published and data presented at the annual meeting of the American Society for Microbiology, Atlanta, Georgia, Mar 7-12, 1982. Abstract title: Inhibition of Clinically Significant Bacterial Organisms In Vitro by 2-Acylpyridine, 2-Acetylquinoline and 1- and 3-Isoquinoline Thiosemicarbazones. A.S. Dobek, D.L. Klayman, E.T. Dickson, Jr. and J.P. Scovill.

DATE: 16 Dec 82 HORK UNIT N	o.: 1913	STATUS: INTERIM	Firm X
STARTING DATE: 22 Jan 1980	DATE OF	COMPLETION: Dec 82	
Key Koros: Antibiotics/bac	terial susceptibil	ity/resistance mech	anisms
TITLE CF PROJECT: Laboratory	y investigation of	new antibiotics	
PRINCIPAL INVESTIGATOR(S): Cha	arles N. Oster, LTC	, MC: Alan S. Cross	, LTC, MC
ASSOCIATE INVESTIGATOR(S): Edit			
FACILITY: HRANC	DEPT/Svc: Medic	ine/Infectious Dise	ase Service
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Cost: AccumuLative St \$13,500.00	IPPLY COST:
FY-83 PEDCASE: CONTRACT COS	T: Supply Cost: \$7,500.00	DATE OF COMMITTEE APPROVAMINAL PROGRESS REPORT	FEB 2 5 1983
STUDY OBJECTIVE: 1. To investigate antibio 2. To investigate	otics against bacte	ria isolated from p	tivities of new atients at WRAMC. ntibiotic resistance.
TECHNICAL APPROACH: In vit		tivities of antibio	tics are determined
PROGRESS BURING FY-82: See f script entitled "Suscept	ibility of antibiot	ic resistant Gram-n	egative bacteria to
heta-lactamase-stable ce Murmen of Suguects Studied: In	<u>phalosporins" which</u> ternal Medicine.	we have submitted	to the Annais of
N7.	A (TO DATE) <u>:</u>	BEFORE COMPLETION OF	ציפּטד <u>:</u>
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPAT	ING IN PROJECT(IF HONE SO	STATE):
CONCLUSIONS: Based on in v may be useful for the tr infections; ceftazidime Enterobacteriaceae infec	eatment of antibiot and ceftizoxime may	ic-resistant Pseudo:	monase aeruginosa
PUBLICATIONS OR ABSTRACTS, FY-Dobek AS, Oster CN, Croresistant Gram-negative Submitted to the Ann In	ss AS, Dickson ET J bacteria to beta-1	ir. Susceptibility actamase stable cep	of antibiotic halosporins.

DATE: 25 Jan 83	Hose ther No.:	1914	SIATUS	: Interim x	Firm.
STARTILE DATE:		DATE O	F COMPLET	10:1:	
		biotics; joint			
TITLE CF PROJECT: ministered by t	The evaluati the intraveno	on of Ceforanidous route, as pro	e (IND ophylac	12762) vs Ceph tic agents in	nalothin, ad- patients under-
going hip or kr	iee arthropia	isty.	 -		
PRINCIPAL INVESTIG	ATOR(s): Edmun	d C. Tramont, Co	DL, MC		
ASSOCIATE INVESTIG	ATOR(s): MD Tr	emaine, CN Oste	r, JW Bo	oslego, WM Ber	rger, ER McKinstry
FACILITY: KRAYE	····	DEPT/Syc: Med/II	OS & S	Surgery/Orthor	pedics
Accurative PECC	SE Cost: A	CCUMBLATIVE CONTRACT	Cost:	ACCUMULATIVE SU	PPLY COST:
	CONTRACT COST:	SUPPLY COST:	DATE OF	COMMITTES APPROV PROGRESS REPORT 2	AL OF 26 Jan 1982
preventing infearthroplasty. TECHNICAL APPROACH prophylaxis.	A prospecti	ve, double-bling of 87 patients versis is underway	in pat	ients undergoi	ing hip or knee
Humber of Subjects FY-82:	STUDIED: TOTAL (TO	DATE): 87	Befor	RE CONSLETION OF S	Srupy: 87
None Conclusions: Over	all infectio	n Subjects Participar on rates between hal report will	the ce	cousct(IF None so	state):
PUBLICATIONS OR ASS	STRACTS. FY-82:				
None					•

DATE: 26 Jan 83 Hosk Liver No.	.: 1915	STATUS: INTERNA X FINAL	
STARTING DATE: 1 Oct 1980	DATE O	DE COMPLETION: 1984	
Key Nords: Fibronectin assa	<u>y</u>		
TITLE OF PROJECT: Fibronection	on Levels in Crit	tically Ill Patients	
PRINCIPAL INVESTIGATOR(S): J	erald C. Sadoff		
ASSOCIATE INVESTIGATOR(S):			
FACILITY: MOANC	DEPT/SVC: Medi	icine/Infectious Disease	
	ACCUMULATIVE CONTRACT		
0	00	· 0	
FY-83 NEDCASE: CONTRACT COST:	: Supply Cost:	Date of Committee Approval Of Annual Progress Report FEB 2.5. 1983	
PROGRESS DURING FY-82: No prog of personnel problems comb We anticipate completion of Number of Subjects Studies:	gress has occurred pined with more in of protocol in FY	d during FY 82 because of a combina mmediate obligations of WRAIR dution 84.	ati es.
FY-82: TOTAL ((TO DATE):	BEFORE CONSLETION OF STUDY: 300	
SERIOUS/UNEXPECTED SIDE EFFECTS	III SUBJECTS PARTICIPA	ATING IN PROJECT(IF HOME SO STATE):	
None	• *	•	
Concrusions: Pending			
PUBLICATIONS OR ABSTRACTS. FY-82	?:		
None		•	

DATE: 25 Jan 83 Mass Guer R	o.: 1917	STATUS: INTERIM X FIRM	-
STARTILE DATE: 24 Feb 81	DATE OF	OF COMPLETION: 1983	-
KEY Noras: Antibiotics/pro	ophylaxis/neurosurg	rgery	-
TITLE OF PROJECT: Prophylad	ctic antibiotics in	in neurosurgery: a prospective,	ı
randomized, double-blind	, and placedo conti	trolled Study.	_
PRINCIPAL INVESTIGATOR(S): WJ	Morris and CN Oste	ter	-
ASSOCIATE INVESTIGATOR(S): ED	George, DE McDowe	ell, AS Dobek, EC Tramont, ER Mc	kinstry
FACILITY: KRAYE	DEPT/S/C: Med	d/IDS Surgery/Neurosurgery	-
Accumunative PEDCASE Cost:	ACCUMULATIVE CONTRACT 0	T Cost: AccumuLative Supply Cost: \$1,000.00	,
FY-83 PEDCASE: CONTRACT COST	T: SUPPLY COST: \$1,000.00	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT 25 Jan 1982) :
in preventing infections relogical surgery. TECHNICAL APPROACH: Prosprophylactic antibiotics	at the operative pective, double-bl	ness of prophylactic antibiotics site in patients undergoing new lind placebo-controlled trial of in the study. Overall infection	1− F
rates were similar betwe	en antibiotic and	placebo groups.	-
	(TO DATE): 200	BEFORE COMPLETION OF STUDY: 220	<u>-</u>
Serious/Unexpected Side Effects None	s in Subjects Participat	ATTING IN PROJECT(IF NONE SO STATE):	•
Conclusions: The study will rolled. Data will then 1983.	l be terminated af be analyzed and a	fter 220 patients have been en- final report submitted by July	•
PUBLICATIONS OR ASSTRACTS, FY-8	Ω:		-

Francias Joseph Attociete Joseph	-				
FACILITY: 1227'S	X	Parks :	Infe	ctious	Disease
Focumplains PECO		Mura Activa (¥ 1,471	Necessary Costs
PY-83 PYDDASE:	Communication	State Con-	:	14.00 E 14.00 Hz	Colonia de la Arrecta Maria Colonia Colonia de la Arrecta Maria Colonia Colonia Colonia de la Arrecta Maria del Arrecta Maria del Arrecta Maria de la Arrecta Maria del Arrecta Maria del Arrecta Maria de la Arrecta Maria de la Arrecta Maria de la Arrecta Maria del Arrecta Maria de la Arrecta Maria del Arrecta Maria
ousestaff and Tichnich Americ asal swabs'- c	To determine by phage type Phage type ulture - phage	e rate of S ing to iden into popu	S. aur ntify lation	eus co kineti •	lonization among newly and so of introduction with s
ousestaff and Tichnich America asal swabs - c Fronting Diction P	To determine by phage type Phage type ulture - phage Cultures	e rate of sing to identify to into population for the real of the	S. aur ntify lation analys	eus co kineti is of	ionization among newly as cs of introduction with s
Tichnich Arman Tasal swabs - c Freezes Danns F	To determine by phage type Phage type ulture - phage Cultures	e rate of sing to identify to populate type - a completed	S. aurntify lation analys d, ana	eus co kineti is of (lonization among newly and so of introduction with s

DATE: 4 NOV 82 HORK UNIT N	o.: 1919	STATUS: INTERIM XXX FIRM	
STARTING PLATE: 1 Nov 81	DATE OF	COMM ETION:	
NET NORUS. — ———	eningitis Monoclona		
TIME OF PROJECT: Ability Positive E. coli in the or Cerebrospinal Fluid a	Presence of Neonat	ody against E. <u>coli</u> Kl to Kill Kl- al Neutrophils, Using Neonatal Ser ce	- ra
TRINCIPAL INVESTIGATION (3).	LAN S. CROSS, MD, L		
ASSOCIATE INVESTIGATOR(S): N	HENRY WOOLDRIDGE,	MD, LTC, MC	
FACILITY: HRAYC XXX	DEPT/Svc: Medic	ine, (ID) and Pediatrics	
Accumulative PEDCASE Cost:	ACCUMULATIVE CONTRACT C	OST: ACCUMULATIVE SUPPLY COST:	
FY-83 FEDCASE: CONTRACT COS	T: Supply Cost:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 25 1983	
		y against important neonatal of neonatal immune system.	
TECHNICAL APPROACH: In vitr blood, with adult and ne prepared by Dr. Wendell	onatal complement s	PMN from adults and cord ources. Use monoclonal	
PROGRESS DURING FY-82: Esser	itially have shown t	hat the monoclonal antibody t with spinal fluid as a	
MUMBER OF SUBJECTS STUDIED:			
FY-82: 15 TOTAL	(TO DATE): 15	BEFORE COMPLETION OF STUDY: ~17-18	
SERIOUS/UNEXPECTED SIDE EFFECTS	S IN SUBJECTS PARTICIPATION NONE	ng in Project(if nome so state):	
Conclusions: This monoclor treatment of K1 E. coli	nal antibody, if it disease, must work	is to be effective in the at the bacteremic phase.	
PUBLICATIONS OR ABSTRACTS, FY-8	2:		

Ability of monoclonal antibody 2-2-B to kill Kl positive E. coli in conjunction with cord blood neutrophils and sera and neonatal spine' fluid. Abstr. #155, 1982 Interscience Conferences on Antimicrobial Agents and Chemotherapy, Miami, Fla., 1982.

Detail 5 Dec 82 Vession to Scarring Page: October 198	1920	Section 1984 Control October 1984
Ny Description Fever Environme line of Products Environme P. multocida	ental Cooling ental Cooling a	nd survival in Rabbits Infected with
Andrews Investors (1994)		L
Account Institution of the H	erald, William	
FACILITY: 12.7%		Infectious Disease Service
Accumulative PEUGE Cont	Record Alexandra	dental control (Account Actual Reference Control
1Y-83 PETCASE: Compact Com	\$3,550.00	\$3,545.00
Tickness Approach: We are and measuring survival.	e exposing infec	mental cooling has a good or bad
Inches Dans IV M. Pleas	se see attached	
November of Subjects Supply to		and the second of the second o
		Mariotic Consecutivity of Stephen
Shainus/Cosxpectro Stos Estec No	rs in Source office	nomenous in Mich envis none se styre):
Concessions: We have devi to indicate that envir infected animals.	eloped a rabbit onmental coolin	model which shows trends that seem g may increase the mortality of

PROGRESS REPORT FY '82

Work Unit: 1920

- 1. In the last twelve months operative procedures were performed on 26 rabbits. Three rabbits died in the perioperative period probably as a result of the surgical procedure.
- 2. Nine animals were used developing the correct innoculum for an LD-50.
- 3. Seventeen rabbits were used in a pilot study of the model to adjust the temperature of the environment and the innoculum for the correct LD-50.
- 4. The survival data from the Pilot study:

Conditions	# of Animals	Survival Time
Cooled (9°C)	3	74 hours
Infected (10 ⁷ -bugs)	5	80 hours
Infected & Cool (10'-bugs + 9°C)	5	37 hours
Neither	2	96 hours

- 5. The study was interrupted by difficulty obtaining approval from the Animal use committee at WRAIR. We have amended our protocol and upon receiving authorization will proceed with the rabbit study.
- 6. Funding In FY 82 the following expenditures were made in support of the protocol:
 - a) Disposable supplies (tape, sutures, etc.) Cost \$ 801.00
 - b) Capilal items Recorder, Recording thermometers. Cost \$2744.00
- 7. Animal: used in the original pilot study were obtained free from an expired protocol at WRAIR.

	b
DATE: 25 Jan 83 Mass Ever No.: 1921	STATUS: INTERIN X FINAL
01/11/11/0 0/1/2/	CO4-LETION: 1985
Key loss: Macrophage, Leishmania; lymphokini	s; intracellular infections.
TITLE CF PROJECT: Human macrophage activation donovani.	for the killing of Leishmania
PRINCIPAL INVESTIGATOR(S): David L. Hoover and Ch	narles N. Oster
ASSOCIATE INVESTIGATOR(S):	Value (Informations Discours)
FACILITY: KRAYC DEPT/S/C: Medi	cine/Infectious Disease
Accumulative MEDCASE Cost: Accumulative Contract	COST: ACCUMULATIVE SUPPLY COST:
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST: 0 0 \$2,000.00	DATE OF COMMITTEE REPROVAL OF RUNDAL PROGRESS REPORT FEB 25 1983
Study Objective: 1) To investigate macrophage Leishmania as a model for intracellular intracellular activate human macrophages for intracellular TECHNICAL APPROACH: PROSRESS DURING FY-82:	e-parasite interactions using fections. 2) To learn how to ar killing.
Number of Subjects Studied:	
FY-82: 15 TOTAL (TO DATE): 15	BEFORE COMPLETION OF STUDY: 200
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPAT None	ING IN PROJECT(IF NONE SO STATE):
CONCLUSIONS: See Attachment	
PUBLICATIONS OR ABSTRACTS, FY-82:	
See Attachment	

Work Unit No: 1921

PROJECT TITLE: Human Macrophage Activation for Killing of <u>Leishmania</u> donovani.

PRINCIPAL INVESTIGATORS: David L. Hoover, M.D., MAJ, MC
Charles N. Oster, M.D., LTC, MC

Prior work performed in Dr Carol's Nacy's laboratory has characterized the interaction between leishmanial amastigotes and murine macrophages. To test the applicability to a human system of concepts of intracellular killing of Leishmania by murine macrophages, we have initiated a program to examine parasite—macrophage interactions using human cells.

Initial efforts have been directed toward locating appropriate sources of human mononuclear phagocytic cells and establishing systems to investigate infection of macrophages or monocytes and subsequent intracellular replication of parasites. We were interested in obtaining purified monocytes for use in suspension cultures, since the large number of lymphocytes in Ficoll-Hypaque-separated mononuclear cell preparations interferes with accurate light microscopic evaluation of infected cultures. In the first series of experiments, monocytes were purified by counterflow centrifugation-elutriation of Ficoll-Hypaque-separated mononuclear cells obtained from volunteers undergoing leukapheresis. This procedure resulted in a preparation containing about 10⁸ monocytes, approximately 85% pure, with some lymphocyte and neutrophil contamination, but required 10-14 hours for cell collection and separation. Moreover, cells could not be separated without contamination by potentially endotoxin-containing fluids. Although cell viability was excellent, monocytes had deformed

Work Unit #1921

membranes and were sticky. We therefore investigated methods of separating monocytes from Ficoll-Hypaque mononuclear cell preparations using continuous Percoll gradients. This technique resulted in 4-15 x 10⁶ monocytes from 50 ml of blood, with purity of 60-85%. Using either elutriated monocytes or Percoll-separated monocytes, we have defined the kinetics of infection and intracellular replication of the parasite, demonstrating that organisms are rapidly taken up during the first 4 hr. Log-phase replication then occurs for the next 60 hr. In order to determine conditions that optimize the growth of parasites in our system and to provide a basis for further studies of lymphokine-mediated intracellular killing of the parasite, we have also begun to examine the effect of normal and immune serum on uptake and subsequent intracellular fate of parasites in macrophages in suspension culture. Fresh human serum has been shown to kill promastigotes but not amastigotes of L: donovani; the effect of fresh serum on amastigotes and promastigotes of L: tropica is not known. Also not known is whether immune serum influences the interaction of human monocytes or macrophages with parasites.

Preliminary studies have also been performed on the mechanisms of activation of human monocytes for the killing of Leishmania: These results have not been encouraging, although others have demonstrated that L: donovani can be killed by monocyte-derived macrophages exposed to lymphokine-rich supernatants of lymphocyte cultures. A number of sources of mediators must be examined before we can conclude that monocytes are refractory to lymphokine-mediated intracellular killing; studies in the murine system, however, suggest that young mononuclear phagocytes, including blood monocytes, respond poorly to lymphokines.

272

Work Unit #1921

To overcome the potential problem of unresponsiveness of human monocytes to lymphokines that mediate intracellular killing, we have also initiated studies on human peritoneal cells. Macrophages have been collected from women undergoing diagnostic laparoscopy.

Preliminary data indicate that these cells will support the growth of L: tropica: Characterization of these macrophage populations, however, suggests that most samples represent a mixture of resident and inflammatory macrophages, even in women who appear normal at operation. As previously noted for murine cells, peroxidase positive human macrophages are more susceptible to leishmanial infection than are peroxidase negative cells. The ability of these cells to respond to lymphokines for intracellular killing is currently being examined.

Our efforts are currrently being directed toward continued survey of cytokines for activities that enhance microbicidal activity of human monocytes and peritoneal macrophages. Once such mediators have been detected, we also intend to investigate the mechanisms of their effect and potential modulating effects of antibody in intracellular killing by lymphokine-treated macrophages and monocytes. Such studies may have considerable relevance to the development of immunotherapeutic regimens or vaccines.

Unpublished abstract:

Oster CN, Hoover DL, Nacy CA, et. al. <u>Leishmania tropica</u> growth in purified human monocytes and human peritoneal macrophages. 31st Annual Meeting of the American Society of Tropical Medicine and Hygiene, Cleveland, OH 1982.

Principal Invariance	3. Bruce McClain,	A. Do	bek
Associate Investigators	Par/Sec: Infect		Disease Service
Accomplative PERUSE Co	pari - Accumentations Continuer C	J57:	According the Assault Southern Cooks
FY-83 PEDCASE: Confi	%2,500(projected)	Parks	Countries for over Ca Processa Review FFR 2.5 100
Suby Studentive: To	develope an ELISA for Lyme	e orga	nism
Suby Subscrive: To	develope an ELISA for Lyme See attached sheet.	e orga	
Study Structive: To TEXTHISM AMERICAN FROM SERVICE STRUCT LOUGHA OF SOURCES STO	develope an ELISA for Lyme See attached sheet.		
Stor Stractive: To TEXTHECE AMEDIES FLOORISS DURING FY 87: Louises of Spaniers Stor FY-2: 2	develope an ELISA for Lyme See attached sheet.	Euro	on Versit star on Situal 2002

PROGRESS REPORT FY 82

Work Unit - 1922

- 1. We have received the Lyme Arthritis organism and have been able to propagate it in vitro.
- 2. We have innoculated 12 rabbits with Lyme organism and adjuvant and have been able to demonstrate seroconversion of the rabbits by use of Indirect Immunoflourescent Technique. We have performed blinded tests on the same rabbit sera and have been able to detect pre and post immunization sera in a blinded fashion.
- 3. We have received serum from Dr. Jorge Benash in New York who has documented a positive serologic reaction by indirect immunoflourescence in a patient with a compatible clinical syndrome for Lyme disease. Using that sera we have developed a sensitive enzyme linked assay which can detect antibody out to 1:20,000 using whole spirochete as the antigen. We have tested two sera from patients and found one of them to be positive by our assay.
- 4. We plan to perform the assay on the sera of 300 recruits from Fort Dix New Jersey to develop a standard curve of the amount of antibodies present.
- 5. We plan to develop a flourescent assay for the Lyme arthritis organism.

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Principal Lower Carrow (*) Aucociate Investigator (*)		ruce McClain obek		
FACILITY: 120VC			Infectious	Disease Service
Accumulative REDUASE Co.	st: 16	осырдануу Сель	est hart	7 DECOMP. ARTHS SOURCY COST: \$200.00
FI-83 PEDCASE: Control	ACT COST:	Saway Cour:	PARE OF PLANE	Сомы нас Линарум, С.: Вызычения РЕВ 2.5. 1983
Share Gauctive: To TMP/SMX and Rifam	pin.		frequent	synergy between
Transition Aireonais Do	synergy	studies.		
Incoress Denno 1Y-82:				
S.	ee belo	w.		
Paissa of Chartots Stud	160:	A MARIE C. M. GARRES C. C.		The second section of the section of the second section of the section of the second section of the secti
FY-CO:	Torse (re	्रिस्या इ	Becc	NE Copyright on Study:
				hower(in none or athir):

Progress During FY-82:

- 1. We have examined using the methods described in the protocol around 600 organisms for synergy between TMP/SMX and Rifampin. We found synergy in 5% of isolates in the therapeutic range of the agents being examined. This combination may occasionally be useful but it is so infrequent that the phenomenon is not reportable.
- 2. We would like to close out this protocol.

DATE: 8 Oct 82 MORK BALT IN	0.: 2000	STATUS: INTERIM	x Fron
STARTING DATE: 1978	DATE OF	COMPLETION: Indefi	nite
Key Hords: Stomach, Surge	ry. Gastrointestin	al peptides	·· ·······
	cts of gastric surg		
PRINCIPAL INVESTIGATOR(S): Joh	nn W. Harmon, LTC,	MC, USA	
ASSOCIATE INVESTIGATOR(S): Lav	rence Johnson, COL	, MC, Ian Taylor	
FACILITY: HRANC	DEPT/Svc: Surge	ry - Medicine	
ACCUMULATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT	Cost: Accumulative	SUPPLY COST:
FY-83 FEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APP ANNUAL PROGRESS REPOR	PEB 2 5 1983
STUDY OBJECTIVE: To determine the vagus in the release			astric antrum and
TECHNICAL APPROACH: To commeal, before and after	pare serum levels o gastrointestinal su		response to a
PROSRESS DURING FY-82: 6 add: had Zollinger Ellison synto this study.	itional patients we ndrome which adds a	re studied. 4 of nother potentiall	these patients y important aspect
MUMBER OF SUBJECTS STUDIED:	Indefinite		
FY-82: TOTAL	(TO DATE):	BEFORE COMPLETION	OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPAT	ING IN PROJECT(IF HONE	SO STATE):
None			
CONCLUSIONS: Satisfactory	progess		
PUBLICATIONS OR ABSTRACTS, FY-	82:		

DATE: 19 Jan 83 Hask Uver No	o.: 2002	STATUS: INTERIM	Firm XX
STARTING DATE: 1980	DATE OF	COMPLETION: Indef:	inite
Key Nows: Pancreatic Surg	ery, insulin		
TITLE OF PROJECT: PANCREAD	TIC ISLET PRESER	RVATION	
PRINCIPAL INVESTIGATOR(S): JO	hn W. Harmon		
ASSOCIATE INVESTIGATOR(S):			
FACILITY: NRAYC	DEPT/SVC: Sur	gery	
Accumulative MEDCASE Cost: none	ACCUMULATIVE CONTRACT	Cost: AccumuLative	SUPPLY COST:
FY-83 FEDCASE: Confract Cosnone	T: Supply Cost:	DATE OF COMMITTEE APP ANNUAL PROGRESS REPOR	ROYAL OF F FEB 25 1981
	op methodology to splantation	preserve pancreat	ic islets
	opreserve pancreati	c islet tissue ob	tained from
orig	progress was made og ginal principal inv one is now availabl	estigator left th	e army and
Number of Subjects Studied:			
FY-82: none Total	(TO DATE):	BEFORE COMPLETION	OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECT:	S IN SUBJECTS PARTICIPAT	THE TH PROJECT (15 HONE	: (STATE):
Conclusions:			
none			
FUEL CATTONS ON ABSTRACTS, FY-E	32:		

none

	_			
DATE: 5 Oct 82 HORK UNIT	No.: 2003	STATUS: IN	ITERIM X	FINAL
STARTING DATE: 1980	DATE OF	COMPLETION:	Indefini	Lte
Key Nords: Neogut, short Time of Project: Use of copolymer as a 1			nal Surgen	;y
PRINCIPAL INVESTIGATOR(S): Jo	hn W. Harmon, LTC			
ASSOCIATE INVESTIGATOR(S): B	arbara Rass. CPT. MC	<u>. </u>		
FACILITY: KRAYC	DEPT/SVC: Surge	ry		
Accumunative MEDCASE Cost:	ACCUMULATIVE CONTRACT	Cost: Acc	CUMULATIVE S	UPPLY COST:
FY-83 MEDCASE: CONTRACT CO	ST: SUPPLY COST:	DATE OF COM ANNUAL PROSE	HITTEE APPRO RESS REPORT	VAL OF FEB 2 5 198)
STUDY OBJECTIVE: To expand the surface of TECHNICAL APPROACH:	f the small intesting	ne .		
To develop techniques i	n rabbits to grow sm	nall bowel	mucosa	
PROGRESS DURING FY-82: A me abdominal wall pedicle in Surgery 91:293-300. Humber of Subjects Studied: N	flaps. Studies usin			
FY-82: Total	L (TO DATE):	Before Co	SO KOTTELINA	STUDY:
SERIOUS/UNEXPECTED SIDE EFFEC	TS IN SUBJECTS PARTICIPAT	ING IN PROJEC	T(IF HONE S	O STATE):
N/A	· ·			
Conclusions:	· — — — — — — — — — — — — — — — — — — —		-	
Satisfactory Progess				
·				

PUBLICATIONS OR ABSTRACTS, FY-82:

1. <u>Surgery</u> 91: 293-300, 1982 2. <u>Surgical Forum</u> 32:81-84, 1981

Explanation for changes in the budget for CIS Project #2003

Use of a Copolymer as a Lattice for Growth of Neogut.

PI John W. Harmon, LTC, MC

John W Harown

The project for growth of neogut is directed at developing a strategy for expanding the surface area of the small bowel to allow adequate absorption of nutrients in individuals who have "short bowel syndrome". Short bowel syndrome can result from trauma, vascular compranise, or intrinsic bowel disease such as Crohns disease.

We were directed by BG Garrison Rapmund to seek CIS funding for this project in 1979. Accordingly we submitted a CIS proposal and it was approved. In FY 1981 and 82 we were authorized \$4600 per year for this project, but for administrative reasons we did not spend the money. In 1981 we also attempted to hire a technician for this project, but again were unable to accomplish this goal.

In August of 1982 CPT Barbara Bass arrived at WRAIR and she has started work on the neogut project. For her work we are ordering consumable supplies and animals with CIS funds. With the assistance of WRAMC CIS the administrative approach to purchasing through CIS is now working very well.

The approach to growing neogut has developed over time and now includes 2 basic thrusts. The first is to disperse rat small bowel mucosal cells, grow them briefly in tissue culture, and then implant them in Gelfoam squares in allogeneic hosts. The second is to transplant whole fetal small bowel into allogeneic adult hosts.

Two publications emanating from this project are attached.

DATE: 20 Jan HORK UNIT !	o.: 2004	STATUS:	INTERIM	Firm XX
STARTING DATE: START	1980 DATE OF THE PROPERTY TESTS OF THE PROPERTY OF THE PROPERT	COMPLETIO	n: Dec 19	80
Key Noos: Analgesics	morphine, anes	thetic	technique	s, epidural
Title of Project: Epic	lural Morphine a	and Vent	tilatory I	narcotics Orive
in I				
PRINCIPAL INVESTIGATOR(S):	ROBERT L. WATSO	ON, COL	MC	
ASSOCIATE INVESTIGATOR(S): D	ennis D. Doblar	CPT M	C, Abbrec	t, Reynolds
FACILITY: WAYE		Ç.	Muldoon	& Operative
ACCUMULATIVE PEDCASE COST:	ACCUMULATIVE CONTRACT	Cost:	Service SACCUMULATIVE	SUPPLY COST:
0	. 0		0.	_
FY-83 FEDCASE: Contract Cos	ST: SUPPLY COST:	DATE OF C ENHUAL PR	COMITTEE APPRODES REPORT	OVAL OF Apr 83
STUDY OBJECTIVE: To meas produced by the adm	inistration of :	ventila Epidura	tory cont 1 Morphin	rol in man. e for the
TECHNICAL APPROACH: Open s	tudy using pati	ents as	their ow	n control.
After epidural loca	l anesthesia, l	hr and	6 hrs po	st epidural
morphine injection.				
PROSRESS DURING FY-82:			1000	
S	tudy completed	Decembe	r 1980.	
HUMBER OF SUBJECTS STUDIED:				
FY-82: 10 Total	(TO DATE):	Before	COMPLETION OF	· Stuby:
SERIOUS/UNEXPECTED SIDE EFFECT	S IN SUBJECTS PARTICIPA	ring in Pac	DECT(IF NONE	SO STATE):
Course Vantilatory	reenange blunt	ing occ	ure one a	nd six hours

CONCLUSIONS: Ventilatory response blunting occurs one and six hours post epidural morphine injection without correlation to the serum morphine levels. Response is not significantly different from that of parenteral morphine, although analgenic persists for 8 - 25.5 hrs.

Publications or Abstracts. FY-82: Study won Young Investigators Award at Annual Postgraduate Assembly of Anesthesiologists in New York City, Dec 1980.

CHAPO SEDOMENO		
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WORK UNIT #2005

REPORT AUS ON OTHER DYMBE.

ters of another, and the transfer of the community of the control of Introduceator ledaxolog as a Fre-Alasth the Methotics on los in Aljunat to Intravenous Midazolas, Blic, at A are Weigelin Amosthesia Industion.

HS II -- NO

TO Clim Lavent Svo, WRAMC

FROM C, Ames & Open Sve

28 Mar 1933

COL Walsbirter / July 1471

- 1. The inclosed letter to Jay Miller of Hofrman-Lakophe, The., decreasing the president termination of our study on 8 Morch 1982.
- 2. A signed notice of Investigational Drug Disposition was forme let on 17 Feb (MC ral a dru count was verified by the Assa Chief of the Firmmany Service (W.O. Hinee, Jr., 1981, W.C.), was returned all used and unused drugs to Mofitan-LaRoche, Inc.
- 3. Part of the study was blind (intrasposalar propolication) and part of the study we have (incravenous industion).

Caly six completed patients were reported. In all of the patients, no unlowed this offects were noted, and in the open part where Midazelan was administed Timerawards dy, that was a merked sedation of the diagonal type, but without signs of verope irritation see with no significant changes in cardiovascular response.

None of the patients receiving the blinded intraspecular partitions evidenced any state \$00 tissue (skin or muscle) irritation when followed up to 48 hears (set-ie) stice.

In surmary, the open part of the study revealed Middle Log to be a very weeful draw to be hither as an industion agent or as an intravenous sedablive adjusce to projected resistant entablesia. The blinded premadicant will have to be judged on statistical most when the ionic is broken; however, patient acc planes of the color medication was good, with sta jectives of pain on injection and without signs of tisses irelation.

ROBERT L. WATSON, NO

COL, MO

Chief, Ames & Open Sve

2 Tuels

1. Mr. 8 Mar. 82

2. Form 914

Copy available to DTIC ' peimit fully legible repledue if .



DEPARTMENT OF THE ARMY WAY, OR TOLD ARMY TO DICAL OF THE WASHINGTON, D.C. 2012

REPLY TO ATTEMPTION OF:

HSWP-SAO

8 March 1982

Jey D. Miller Clinical Research Coordinator Department of Medical Research Hoffman-Lakoche Inc. Nucley, NJ 07110

Dear Mr. Milles:

Thank you for your phone call of 6 March 1982 and partification that all Midazolam studies were being discontinual so as to allow for conjutting and collation of statistical data prior to filling on PMY with the PT, on Midazolam.

I hope that the few positions (S, sin consideration for mental positions of help to you in gaining favorable consideration for mental the very useful droubled with solution.

In all of our primers we need my nationary sides of some and in the open part where we admissioned filders has interested by a result of the results was needers to be marked to define as the specific party, but with it signs of venous irritation and with no signific of charges in small section response.

Note of the patients receiving the blinded introduced by a line to the denced any signs of tissue (whin or muscle) includes a for up to 40 bees post-injection.

In summary, the open part of the study reverted Midevolus to be a very useful drug to use either as an induction agent or as an intraverses solutive adjunct to projected regional anothetic procedures. We blind a promisent will have to be judged on statistical resistant then the order is broken; however, patient acceptation of the coded redication was good, without comment of pain on injection and without a gas of tissue irritation for up to 48 hours following injection.

The remaining drug is being shipped back to you under separate cover and by Federal Express.

The following is a list of the drugs used and returned:

	BOX LABEL	USED	QUAN	TITY RETURNED
1.	Study - 1 Protocol 2198 PT 1-10	1-1 (1 amp 2-1 (1 amp 3-1 (1 amp 4-1 (1 amp 5-1 (1 amp 6-1 (1 amp 7-1 (1 amp 8-1 (1 amp) 2-1) 3-1) 4, 1) 5-1) 6-1) 7-1) 8-1	(1 amp) (2 amp) (2 amp)
		TOTAL 8 amp	3	12 au ₄
2.	Study - 1 Protocol 2198 PT 11-20 Label unbroken	None	TOTAL	20 amps (2 ml)
3.	Study - 1 Protocol 2198 PT 21-30 Label umbroken	None	TOTAL	20 aups (2 ml)
4.	Study - 1 Protocol 2198 PT 31-40 Label umbroken	None .	TOTAL	20 atgs (2 ml)
5.	Study - 1 Protocol 2198 PT 41-48	None	TOTAL	16 amps (2 ml)
		GRAND TOTAL 8 am	ps used	Et amps returned
6.	Midazolam 50 mgm (asthehydrochloric 10 ml - 50 mgm F 13 Cll1760-01		als (partial)	14 unbroken vials 2 pertial vials
	•	GRAND TOTAL		16 vials returned

The Investigational Drug Disposition (M914) is also enclosed in this letter and a copy will accompany the shipment of drug.

I assume that the records I have in my file are my copies; however, if this belongs to you, then please inform me and they will also be forwarded.

8 Mar 82 HSWP-SAO

I believe that upon receipt of the enclosed letter, investigational drug disposition form and shipsent of unused drag, that study prote of No. 21005 "An Evaluation of Intramscular Midezolam as a Premotific Madication and as an Adjunct to Intravancus Midakolso, Thiopental and Ketadia Amenthesia Industion" will be closed.

Enclosures **a**3

Robert L. Walton, NO

COL, MC

Chief, Anesthesia & Operation Sve

College Williams The

osmir senge planemon go.



£1314

HOFFMANN-LAROCHE INC.

• NEW JERSEY 07110 • TELEPHONE (201) 235-5060 • (N.Y.C) 385-1400

MEDICAL PERSANCH DEPARTMENT'S DEVELOPINGS MICHAEL AS FAIR A

NOTICE OF INVESTIGATIONAL DRUG DISPOSITION

Date: February 17, 1982

TO: Hoffmann-La Roche Inc.

340 Kingsland Street Nutley, New Jersey 07110

FROM: Investigator's Name: Robert Watson, M.D.

Chief of Anesthesiology

Address:

Walter Reed Army Hospital

P.O. Box 376

Washington, DC 20014

Protocol No: 2198A Test Drug: Midazolar 48-2ml ampuls Midazolar 5mg/ml; 48-3ml ampuls Midazolar 5mg/ml; 48-3ml ampuls Number of bottles shipped: Placebo for Midazolar; 16-10ml vials Midazolar 5mg/m RE:

Number of botdes used: 8 Augs (1-1,2-1,3-1,4-1,5-1,1-1,1-1,3-1), 2 pad Number of botdes used: 8 Augs (1-1,2-1,3-1,4-1,5-1,1-1,1-1,3-1), 2 pad Number of botdes used:

Number of bottles returned: 88 Amps ov 1 14 mount Victor

Lam returning to you all of my remaining supplies of the above-manaed drug.

D I certify that I have exhausted all of my supplies of the above-named drug.

Coherth Water MD

Date: 22 Narch83 Nosk Unit	lo.; 2006	Status: Into	net : <u>Fir</u> ac <u>></u>
South Dett: 20 Pat 20	<u> </u>	gregoring. A	11y 82
Key Voios:			
Title of Product:	·		
Eutorphonol (Sta-	dol) Study No. 30	00-02-1	
PRINCIPAL INVENTIGATOR(S):	RobertKatson,	Mb	
Associate Investigator(s): C	lement . Markaria	eri, CRNA	The control of the co
FACILITY: WRING X	Dayr/Syc: Acos	ghesia Service) The state of the
Accumus arrive MEBUASE Cours No 10	Accume artive Countai None	7 Coort Accuse Not	ALIVE SOURLY COST:
FY-83 FEECASE: COMPACT CO.	or: Supery Cont.	Date of Corner of Friedry Phograps	ir Komory C. Regga <u>20 nop 19</u> 50
TECHNICAL REPRONCES	brative Wawlgesie.		rempto ma to bilanced treas
· · · · · · · · · · · · · · · · · · ·	(10 DATE): 26	Boroke Color	Exton of Stooy:
SURTOUS/UNIXVECTED SHIE EFFECT NONE	s in Subjects Particles	mma in Perusa G	F NORT SO WARE);
agent provided generall;	y smooth intraope: decreased blood lo	chive course : evel based or ;	(2)The Time of advertice is of the countries of incident according for some words.
PUBLICATIONS OR ASSIRACTS. FY-	S2:	<u> </u>	the second second second
SEE ATTACHED BRISTOL SE	ATISTICAL REVIEW		

DATE: 20 Feb 83 Mosk UNIT No.	.: 2007	STATUS: INTERIN X	Fire
STARTING DATE: June 1981	DATE OF	Caraction:	
Key Norge: Skeletal Muscl	e, Contracture Res	ponse of Skeletal	Muscle
TITLE OF PROJECT: In Vitro	determination of	the response of sl	celetal muscle
to caffeine, halothane &	caffeine plus hale	othane	
PRINCIPAL INVESTIGATOR(S): R	OBERT L. WATSON, M	D. COL, MC	
ASSOCIATE INVESTIGATOR(S): W	ILLIAM KEEFE, MD -	SHEILA MULDOON, N	4D
FACILITY: HRAYE X	DEPT/Syc: Surg	ery/Anesthesia	
	ACCUMULATIVE CONTRACT C	OST: ACCUMULATIVE	SUPPLY COST:
FY-83 PECASE: CONTRACT COST:	: Supply Cost:	DATE OF COMMITTEE APPR MINUAL PROGRESS REPORT	OVAL 0F FER 2.5 1983
STUDY OBJECTIVE: To deter caffeine of indiv	mine response of n & halothane. Thi riduals who have ex	ormal skeletal mus s will be compared perienced maligna	scle to drugs, i with response nt hyperthermia
TECHNICAL APPROACH: Isometri for basi	c tension measuring determination, constochemistry sect	g apparatus at U.: ollaboration with	S.U.H.S. is use Bethesda Naval
Total	expanded to includ studied contractur lel studies on dog	e tests is now 32	subjects.
Number of Subjects Studied:			
FY-82: 4 TOTAL ((то рате): 9	_ BEFORE COMPLETION C	¥ Sזעפא <u>י:</u>
SERIOUS/UNEXPECTED SIDE EFFECTS	IN SUBJECTS PARTICIPATIO	HIS IN PROJECT(IF HOME	SO STATE):
None		·	
clinical hist caffeine cont	lation of halothane tory of MH appears tracture test appea positive rate.	to be present. H	alothane
PUBLICATIONS OR ABSTRACTS. FY-82	?: None		

DATE: 8 Apr 83 Hoak livet No.: 2009	STATUS: INTERIN FIRM XXX
STARTING DATE: Date of	COMMETICAL Never completed, Investigators
Key Horas:	PCS'd.
TITLE OF PROJECT: Venous Sequelae Following	Intravenous Lorazepam
and Diazepam.	
Patricia A. Stipet: PRINCIPAL INVESTIGATOR(S): Tom Fusco, CPT, AND	ich, CPT, ANC
ASSOCIATE INVESTIGATOR(S):	
FACILITY: MRAYE DEPT/SVC: De	pt of Surg - Anes & Oper Svc
ACCUMULATIVE PEDCASE COST: ACCUMULATIVE CONTRAC	T COST: ACCUMULATIVE SUPPLY COST:
FY-83 PEDCASE: CONTRACT COST: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT
STUDY DBJECTIVE:	
TECHNICAL APPROACH:	
PROGRESS BURING FY-82:	
Humber of Subjects Studied:	
FY-82: TOTAL (TO DATE):	BEFORE COMPLETION OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPA	ATTING IN PROJECT(IF NONE SO STATE):
CONCLUSIONS: PROJECT WAS NEVER STARTED.	
PUBLICATIONS OR ASSTRACTS, FY-82:	•

MAIN SUMMARY SHEET

APPLICATION FOR CLINICAL INVESTIGATION PROJECT

1. PRINICIPAL INVESTIGATORS:

Patricia A. Stipetich, CPT, ANC, Student, School of Anesthesiology Nursing, WRAMC.

Tom Fusco, CPT, ANC, Student, School of Anesthesiology Nursing, WRAMC.

- 2. PROJECT TITLE: Venous Sequelae Following Intravenous Lorazepam and Diazepam
- 3. OBJECTIVE: To compare lorazepam and diazepam in terms of incidence of venous sequelae following intravenous injection.
- 4. MEDICAL APPLICATION: Previous studies have thus far indicated a lesser degree of patient discomfort when receiving lorazepam than with diazepam. Lorazepam additionally appears to provide a longer duration of action and a greater degree of perioperative amnesia.
- 5. STATUS: Refer to attached Research Proposal, section titled Review of Literature.
- 6. PLAN: Refer to attached Research Proposal, section titled Methodology.
- 7. BIBLIOGRAPHY: Refer to attached Research Proposal, section titled Bibliography.
- 8. FACILITIES TO BE USED: Will conduct preoperative and postoperative patient anesthesia interviews on clinical wards.
 The administration of the drugs will occur within the
 Operating Room facilities.
- 9. TIME REQUIRED TO COMPLETE: Anticipate beginning and completion of research project in November 1981 and August 1982 respectively.
- 10. PERSONNEL TO CONDUCT PROJECT: Principal investigators as above.
- 11. FUNDING IMPLICATIONS: NA

DATE: 1 OCT 82 HORK UNIT N	o.:#2010	STATUS	XXXXXX	FIRAL	
STARTING DATE: 1DEC81	DATE OF	(UMOLET	10N: 30SEP8	32	
Key Nords: Anesthetic ga	ses, vital capa	city			
TITLE OF PROJECT: A Study	of Humidified A	nesth	etic Gases	and	
Postoperative Vital	Capacity Measur	ement	S 		
PRINCIPAL INVESTIGATOR(S): CPT ASSOCIATE INVESTIGATOR(S):	lderwood, Phili ANC; Remingtor	p CPT i. Ken	ANC; Calineth CPT	rider, Randal	.1
ASSOCIATE INVESTIGATOR(S):	tero, Flances of	- ANO			
FACILITY: WRAYE	DEPT/Svc: Dept.	of N	ursing/And	esthesia Svc.	
ACCUMILATIVE NEDCASE COST:	ACCUMULATIVE CONTRACT O	Cost:	ACCUMULATIVE	SUPPLY COST:	
FY-83 I'ECCASE: CONTRACT COS	T: Supply Cost:	Date of Annual	COMMITTEE APP PROGRESS REPOR	ROVAL OF T 28NOV81	
STUDY OBJECTIVE: To determ and humidified anest TECHNICAL APPROACH: Measure at 30, 60, 90, 120 m	chetic gases. ement of vital c	apaci	ties preor	and postop	
(one group with dry	anesthetic gase	s and	the other	with humidif	ied.
Progress During FY-82: study					
MUMBER OF SUBJECTS STUDIED:					
FY-82: 15 TOTAL	(TO DATE): 15	Befo	RE COMPLETION	ог Ѕтиру: О	
SERIOUS/UNEXPECTED SIDE EFFECT NONE	S IN SUBJECTS PARTICIPAT	irig in P	ROJECT(IF NONE	SO STATE):	
CONCLUSIONS: Final concluing paper. Preliming ference between pathumidified gases administration of the conclusion of th	ary conclusions ients' vital cap	find aciti	no signifi	icant dif-	
PUBLICATIONS OR ABSTRACTS. FY-	22: NONE present	Ly	-		

DATE: 3 Jan 83 Mosk Unit No.: 2111 STATUS: INTERIM X FINAL STARTING DATE: March 1982 DATE OF COMPLETION: December 1983
STARTING DATE: March 1982 DATE OF COMPLETION: December 1983
Key Moros: Stroke/Carotid Endarerectomy
Time of Project: Subclinical Stroke Following Carotid Endarerect
PRINCIPAL INVESTIGATOR(S):
ASSOCIATE INVESTIGATOR(S): G.P Clagett, Jeffery Black, William Smith
FACILITY: WRANC DEPT/Syc: PVS (Neurology/Radiology)
ACCUMULATIVE PEDCASE COST: ACCUMULATIVE CONTRACT COST: ACCUMULATIVE SUPPLY COST:
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST: Date of Committee Approval Of Annual Progress Report FEB 2 5 1983
STUDY DELECTIVE: To detemine the incidence of subclinical stroke following carotid endarerectomy.
TECHNICAL APPROACH: pre and post carotid endarerectomy neurolgic examinations and CT scans.
PROGRESS DURING FY-82: Poor, frequent scheduling proglems in OR + CT CT scans.
Hurses of Susjects Studied: Calendar yr Calendar yr FY-82: 8 Total (TO DATE): 8 Before Confletion of Study: 50
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT(IF NONE SO STATE):
None
Conclusions:
None to date.
Publications of Abstracts, FY-82:

Work Unit Number: 2106

Interim Report

Title of Project:

Management of the Hemodynamically Significant,

Asymptomatic Carotid Bruit

Investigators:

Principal: LTC G. Patrick Clagett

Objectives: (1) To determine the most appropriate management of patients with asymptomatic, hemodynamically significant carotid bruits, (2) to determine the natural history of asymptomatic extracranial vascular disease, (3) to determine the role of non-invasive diagnostic techniques in the management of patients with asymptomatic extracranial vascular disease.

Technical Approach: Consenting patients who are asymptomatic for cerebrovascular disease who have hemodynamically significant carotid stenoses (as determined by non-invasive studies) are eligible for randomization into two groups. Patients ineligible for randomization include those who have had carotid endarterectomy on the side in question, those judged too frail to undergo carotid endarterectomy, and those who don't consent. Patients randomized into the surgical group will undergo arteriography and carotid endarterectomy if an operable lesion is found. Patients randomized into the second group will be treated with aspirin, 650 mg twice daily, and followed closely (every 3 months). If patients in the second group develop symptoms, they will then undergo arteriography and carotid endarterectomy.

Progress and Results: Since April 1979, 50 patients eligible for entry into the study have been identified. Of these, 27 consented to join and 23 have refused. Of those entered, 13 were randomly assigned to the aspirin group and 14 assigned to the surgical group. Of those on medical therapy, five have become symptomatic for cerebrovascular insufficiency on aspirin and have required arteriography. On arteriography, two patients were inoperable; one had an occluded internal carotid artery and the other had diffuse intracranial disease. The remaining three patients had tightly stenotic lesions at the carotid bifurcation and underwent uneventful carotid endarterectomy.

In the surgical group of the 14 patients assigned to this group, one patient refused arteriography and subsequently died. The other 13 patients underwent arteriography. One of these suffered anaphylaxis during arteriography and secondary myocardial infarction. He is currently considered unfit for surgery. The remaining 12 patients have undergone carotid endarterectomy. With the exception of one case in which the patient suffered postoperative subendocardial myocardial infarction, these operations have been uncomplicated. On follow-up, two patients in the surgical group have died. Both deaths were unrelated to cerebrovascular disease.

Conclusion: The number of patients remains too small and the follow-up period too brief to draw firm conclusions. We continue to enter patients into this trial and will continue to do so for at least another year.

Work Unit Number: 2109

Title of Project: Etiologic Factors for Recurrent Carotid

Stenosis

Investigators:

Principal: LTC G. Patrick Clagett

Objectives: (1) To determine risk factors for the development of recurrent carotid stenosis following successful carotid endarterectomy

Technical Approach: Patients with surgically or angiographically proven carotid restenosis comprise the study group. These patients are age and sex matched with patients who underwent carotid endarterectomy during the same year. The second group of patients comprises the control group. On all patients, the following information is obtained: symptoms and other indications mandating first procedure, angiographic findings, operative details, immediate postoperative morbidity and mortality, histopathologic findings, and presence of atherosclerotic risk factors. In addition to these data, study patients and control patients will have blood drawn for determination of cholesterol and triglyceride levels as well as lipid fractionation studies to determine the relative amounts of HDL, LDL and VLDL cholesterol. Furthermore, both groups of patients will undergo threshold dose response platelet aggregometry to ADP epinephrine and collagen.

Progress and Results: 35 patients have been identified with recurrent carotid stenosis following successful carotid endarterectomy. A case-control study has been completed in which 21 patients with recurrent stenosis were age and sex matched with control patients who underwent carotid endarterectomy the same year but who did not have evidence of recurrence. The data were analyzed and the conclusions are listed below.

The next phase of this study is to analyze the histopathologic material. The plan as outlined in the original protocol is to compare the histopathology of the original carotid endarterectomy specimens with the recurrent lesions. In addition, we wish to compare the characteristics of the original specimens with the control patients' specimens to detect any differences in the original atherosclerotic plaques. The co-investigator for this portion of the study is Dr. Max Robinowitz from the Cardiovascular Service of the Armed Forces Institute of Pathology. We are currently retrieving the original slides and paraffin blocks on these patients. To date, we have retrieved material on approximately 20 of the study patients and 10 of the control patients. Microscopic analysis of this material will be in progress during the next year.

Conclusions: To date our studies have led to the following conclusions: (1) Cigarette smoking following carotid endarterectomy is an important risk factor for recurrent carotid stenosis, (2) other atherosclerotic risk factors and hyperlipidemia are common in all patients undergoing carotid

endarterectomy and are not predictive of recurrent carotid stenosis, (3) females are not higher risk of recurrent carotid stenosis and, (4) aspirin and other antiplatelet agents do not appear effective in protecting against recurrent carotid stenosis. These findings were presented in a paper entitled, "Etiologic Factors for Recurrent Carotid Stenosis: A Case-Control Study", at the annual meeting of the International Society for Cardiovascular Surgery and Society for Vascular Surgery, 19 June 1982, in Boston, MA. Abstracts detailing these findings have also been submitted for consideration for presentation at the American Heart Association's 8th International Joint Conference on Stroke and Cerebral Circulation in February 1983. An abstract has also been submitted for consideration for presentation at the annual meeting of the Southern Association for Vascular Surgery in January 1983.

Funding Requirements: To date there has been one travel requirement for presentation of a paper which cost \$300.00

Publications: Clagett, G. Patrick, Rich, Norman M., McDonald, Paul T., Salander, James M., Youkey, Jerry Y., Olson, David W., and Hutton, John E., Jr.: Etiologic Factors for Recurrent Carotid Stenosis: A Case-Control Study. Accepted for publication in Surgery.

Type of Report: Interim

DATE: 10 June 1982	Work Unit No. 2	112	STATUS	: INTERIM	FIMAL XXX
STARTING DATE: Ja		_	COMPLET	ION: Apr '	82
KEY WORDS: Pro	ostatic Valve, St	. Jude		·	
TITLE OF PROJECT:	EVALUATION	OF ST. JUDE VALVULAR	PROSTHES	SIS.	
PRINCIPAL INVESTIG					
ASSOCIATE INVESTIG	SATOR(S): Russ Z				***************************************
FACILITY: WRANC				ERY SERVICE	***********
Accumulative MEDCA	ASE Cost: Ac	CCUMULATIVE CONTRACT	Cost:	ACCUMULATIVE	SUPPLY COST:
FY-83 MEDCASE:	CONTRACT COST:	SUPPLY COST:	DATE OF ANNUAL	Committee Appr Progress Report	OVAL OF FEB 2 5 1983
STUDY OBJECTIVE:	Evaluation of	St. Jude Valvular Pr	osthesis	in selective p	atients.
TECHNICAL APPROACE	As per St. Jud	de protocol.			
NUMBER OF SUBJECTS	STUDIED:				
FY-82: 1	TOTAL (TO	DATE): 12	BEFO	RE COMPLETION (OF STUDY:
SERIOUS/UNEXPECTED None relate		SUBJECTS PARTICIPAT	ing in P	ROJECT(IF NONE	SO STATE):
CONCLUSIONS: Twell time, the last one high-risk cases in any other available	ve St. Jude valve having been imp which this valve e prostheses.	ular prostheses were lanted on 29 Mar 82. e offered favorable	These i Flow char	mplants were us acteristics in	ually chosen in comparison to
occurred, both fro	m other causes.	none of them prosther Seven patients are l	living,:a L. Jude	ll without pros Valve until it	thetic compli- is approved by
		FDA. Thus, we term	nate the	investigation	or this valve.

DATE: 10 June 1982 WORK SAFT No.:		STATUS:	Interin	Final XXX			
STARTING DATE: Jan 179 DATE OF COMPLETION: Apr 182							
KEY WORDS: Prostatic Valve, St.				-			
TITLE OF PROJECT: EVALUATION OF ST. JUDE VALVULAR PROSTHESIS.							
PRINCIPAL INVESTIGATOR(S): Walter H	Brott, COL MC						
ASSOCIATE INVESTIGATOR(S): Russ Zaj	tchuk, COL MC		,				
FACILITY: WRANC	DEPT/SVC: THORAC	CIC SURGERY	SERVICE				
ACCUMULATIVE MEDCASE COST: ACCU	JMULATIVE CONTRACT (Cost: A	CCUMULATIVE S	UPPLY COST:			
FY-83 NEDCASE: CONTRACT COST: S	SUPPLY COST:	DATE OF CO. ANNUAL PRO	MMITTEE APPROGRESS REPORT	IVAL OF			
STUDY OBJECTIVE: Evaluation of St	t. Jude Valvular Pro	osthesis in	selective par	tients.			
AS per St. Jude	protocol.						
NUMBER OF SUBJECTS STUDIED:							
FY-82: 1 TOTAL (TO I	DATE): 12	BEFORE	COMPLETION OF	STUDY:			
SERIOUS/UNEXPECTED SIDE EFFECTS IN S	SUBJECTS PARTICIPAT	ing in Proj	ECT(IF NONE S	GO STATE):			
None related to valve.							
CONCLUSIONS: Twelve St. Jude valvul time, the last one having been impla high-risk cases in which this valve any other available prostheses.	inted on 29 Mar 82.	These impl	ants were usu	ally chosen in			
Three patients died at operation, no occurred, both from other causes. S cations at last follow-up. We do no	even patients are l	iving,:all <u>tlude_Val</u>	without prost	hetic compli- s approved by			

DATE: 28 Jan 83 HORK LINET NO	.: 2207	STATUS	HITERIA YY	FROL	-
STARTILE DATE:	DATE OF	COFLET	ici: Indefi		-
Key Noos: Arteriovenous Arteri	Malformation Mini e, Vascular Emboli	-Balloon zation	n Catheter,	Isobutyl	
Time of Project: Treatment of Vascular Les Isobutyl 2-Cyanoacrylate	sions by Mini-Ball	oon Catl	neterization	and	. ·.
PRINCIPAL INVESTIGATOR(S): Eug	ene D. George; Pau	1 H. Pe	vsner; Sherr	y Brahman	-
ASSOCIATE INVESTIGATOR(S): Deni	nis E. McDonnell				- .
FACILITY: KRATE	I	rosurge	ry	·	=
ACCUPALATIVE MEDICASE COST:	ACCUMULATIVE CONTRACT	Cost:	Accumulative	SUPPLY COST:	
FY-83 PEDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF	Comittee her Progress Repor	ROYAL DE 2 5 198	33
TROY OSJECTIVE: To either resectable otherwise ino tumors of the brain. TECHNICAL APPROACH: Use of I either percutaneously vi intraoperably via inject PROSRESS DURING FY-82: See enclosed sheet.	sobutyl 2-Cyanoacr a a mini-balloon c	ly diff ylate i	n small amou or delivere	lar lesions a	and -
PY-82: 35 gluings in Total 10 patients	. (TO DATE): 28 paties	its Befo	RE COMPLETION	of Study:50 p	atient
Senious/Unexpected Side Effect See enclosed sheet.	IS IN SUBJECTS PARTICIPA	·	ROJECT(IF HOME	SO STATE):	-
בסאכרחפופופ:		•			
See enclosed sheet.	,				
PUBLICATIONS OR ASSTRACTS. FY	-82:			•	
a	. .				

CONTINUATION OF WORK UNIT NO. 2207 - Treatment of Vascular Lesions by Mini-Balloon Catheterization and Isobutyl 2-Cyanoacrylate.

PROGRESS DURING FY-82: We treated a total of 28 patients either surgically or via gluing. During the year, there were no deaths. Thirty-five (35) embolizations on ten (10) patients. One patient seemingly had total obliteration of a mandibular arteriovenous malformation. Again, almost all other patients had subsequent surgical therapy carried out. One patient developed a severe brain stem infoxtion following a repeat attempt at gluing in an AVM which had reoccurred. This patient was subsequently admitted to a nursing home, but she is now slowing improving. A similar patient complication from last year recovered sufficiently to allow surgical resection of his massive AVM, a procedure from which he recovered well. The percentage of patients developing even minor complications has seemingly improved this year, possibly resulting from increased experience and knowledge regarding use of the techniques. (See publications from Walter Reed discussing this.)

SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT: See above regarding serious side effects or death. All of these complications would be expected in dealing with these serious and high risk patients. It should be noted that our overall mortality and morbidity rate is far below nationally published series in treating patients with these lesions.

CONCLUSIONS: The use of Isobutyl 2-Cyanoacrylate as an intravascular agent, delivered either percutaneously via mini-balloon catheter techniques or interoperatively via direct intravascular injection, is a useful surgical adjunct in the treatment of otherwise untreatable high risk vascular lesions. Probably in most situations, IBCA alone is not the sole answer to the treatment of intracranial vascular lesions, since we have had at least one recurrence following seemingly total obliteration.

PUBLICATIONS OR ABSTRACTS, FY-82: (1) Combined
Neurosurgical-Neuroradiological Therapy for Cerebral Arteriovenous
Malformations--The Walter Reed Protocol, edited by Smith, Haerer
and Russell, Raven Press, NY 1982. (2) Presentations of results
and associated findings, American Association of Neurologic
Surgeon's Meeting in April 1982. (3) Review Article in
Neurosurgery, March 1982, "Interventional Radiology Polymer Update
- Acrylic". (4) Several exhibits accepted for current pending
AANS in April 1983. (5) Publication pending for two articles
previously accepted by the American Journal of Neuroradiology.
(6) Dr. George was officially invited to present review of Walter
Reed work and present his recommendations on current management of
these problems to Intracranial Vascular Surgery Session at AANS.
(This invitation was based on the reputation being obtained by
this study at Walter Reed).

ADDENDUM: Would like to add as additional co-investigator or associate investigator Joan T. Zajtchuk, Colonel, MC, Chief, Otolaryngology-Head and Neck Surgery.

		— 	
DATE: 5 OCT 82 NORK WHIT N	b.: 2309	STATUS: INTERIM X FIRM	
STARTING DATE: 27 DEC	1977 DATE O	F COMMETION: June 1980	
	gery, Ocular Traum	na ·	
TITLE CF PROJECT: A Study	of Eye Trauma and	Treatment in the Military	
PRINCIPAL INVESTIGATOR(S):	Howard P. Cupples	, MD, CPT, MC, USN	
ASSOCIATE INVESTIGATOR(S):	Paul V. Whitmore,	MD, COL, MC, USA	
FACILITY: HRAYC	DEPT/SVC: Opht	halmology Service. Depart of Su	irgery
Accumulative MEDCASE Cost: 0	ACCUMULATIVE CONTRACT	COST: ACCUMULATIVE SUPPLY COST:	
FY-83 I'EDCASE: CONTRACT COS	T: SUPPLY COST:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983	
by vitreous surgery with by conventional methods. TECHNICAL APPROACH: A serie	the results of oc Todevelop plans s of cases of ocul es will be compare	reous surgery in the management esults of ocular trauma cases managed in the for efficient management of ocular trauma managed by vitreous sed with a similar series drawn during the Vietnam era and managemputer terminal has been made a	ne past nlar (cont'd) surgery
PROSRESS DURING FY-82: All p been completed and the be presented at the Ame	rospective cases d results of this se	done by vitrectomy techniques have a series are the subject of the particular and the par	(cont'd)# oer to
Humber of Subjects Studged: FY-82: Total	(TO DATE):	BEFORE COMPLETION OF STUDY: 100	
Serious/Unexpected Side Effects serious unexpected side management.	S IN SUBJECTS PARTICIPA effects to vitreou	TING IN PROJECT(IF NONE SO STATE): No is surgery have been found in the	1 e
CONCLUSIONS: The results of such sever techniques and these resinstitutions. Loss of emethods have historicall with cases matched for t	ely injured eyes c ults compare almos yes with certain t y run greater than ype of injury will	series suggest that more than team be salvaged with vitreous sust identically with results from types of injuries treated by presults. In our study, comparison be made upon completion of the	rgical other vious with
for publication in RETIN	32: 103 consecutive ca A, September 1982.		
		Management of Intraocular Foreig Malter Reed Ophthalmology Postgr	
STUDY OBJECTIVE (cont'd) collected during the stu	: combat injuries dy.	based upon the analysis of data	
TECHNICAL APPROACH (cont gathering and tabulating	g the retrospective	linic, NNMC and we are currently cases.	y
	291		

NATE: 5 Oct 82 N	logs ther No.	: 2310	STATU	S: INTERIM X	Final
STARTIONS DATE: 13	April 78	, 	BATE OF COMME	TION:	
KEY WORDS:				·	
TITLE OF PROJECT:	MA	J Thom S. T	homassen		
	LT	C Kenyon K.	Kramer		
PRINCIPAL INVESTIGAT		C Fleming D	. Wertz		
ASSOCIATE INVESTIGAT	rox(s):		 		
FACILITY: KRAYC		DEPT/SVC:	Ophthalmo	logy Service	
Accumulative MEDCAS	E Cost:	AccumuLative (CONTRACT COST:	ACCUMULATIVE	SUPPLY COST:
FY-83 MEDCASE: Co	ONTRACT COST	: SUPPLY COST	DATE O	F COMMITTEE APPA PROGRESS REPORT	FEB 2 5 1983
STUDY OBJECTIVE: treatment of a		te intraocu	lar lenses w	ith regard to	safety in the
at the time of	cataract	extraction (or in a seco	nd operation	ected patients eithe following cataract udy to determine the
PROSRESS DURING FY-	82:			(incidence	of adverse effects.
HUMBER OF SUBJECTS	STUDIED:				
FY-82 <u>: 46</u>	TOTAL	(TO DATE): 1	34 BEI	ORE COMPLETION	of Study: unknown
SERTOUS/UNEXPECTED	SIDE EFFECTS	IN SUBJECTS P	ARTICIPATING IN	PROJECT(15 NONE	SO STATE):
None					
CONCLUSIONS:					
Exceprotocol.	ellent res	ults indica	te sufficier	t value to co	ontinue with this
PUBLICATIONS OR ABS	STRACTS, FY-8				
		None.			

FORM

For use of this form, see AR 340-15, the prope

REFERENCE OR OFFICE SYMBOL

SUBJECT Annual Progress Report: FY 82, Clinical Investigation Program, Work Unit #2311

HSHL-SI

"Lyophilized Fascia Lata for Ptosis Surgery"

Č, Dep Clin Invest, WRAMC

FROM Ophthal Svc, DATE

CMT I

WRAMC

14 January, 1983 Dr. Katz:fkm 6/1964

- 1. Reference above Work Unit, one additional case has been performed at Walter Reed Hospital. Patient's name is Bainbridge, Charity, dependent ssan: 170-44-2751.
- 2. Diagnosis: congenital ptosis, bilateral frontalis sling using lyophilized fascia lata was performed without complications. At this time, patient is still being followed.
- 3. Dr. Broughton has published the initial report of the fascia lata study.
- 4. The technical approach has not been modified currently and no serious and unexpected side effects and complications have been met with.
- 5. The study at present is continuing under the same director.

Norman N.K. Katz. MD

COLONEL, MC US ARMY

Ophthalmology Svc, WRAMC

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT Annual Progress Report: FY-82, Clinical Investigation Program, Work Unit #2312, Amsler Grid/Laser Interferometry Study Assessment of Visual Acuity Pre and Post....

HSHL-SI

TO: C, Dep Clinical Invest. WRAMC

FROM MAJ Thom S. Thomassen, MOATE
Ophthalmology Service

17 JAN 1983 CMT TST/tb/61966/67

1. CPT Raysor has left Walter Reed Army Medical Center and did not work on this project.

2. Since CPT Raysor has left WRAMC, with no one to take his place, this study can be terminated for the present time.

Thom S. Thomasten, MD
MAJ, MC, US ARMY
Ophthalmology Service
Walter Reed Army Medical Center

For use of this form, see AR 340-15; the proponent agency is TAGO.

SUBJECT Annual Progress Report: FY-82, Ulinical Investigation Program, Work Unit #2312, The Incidence of Cystoid Macular Edema Fost Cataract Extraction.

TO C. Dep Clin Invest

FROM CFT Charles S. Tressley, MC 17 Jan 83 CMT1 Ophthalmology Svc

Shortly after receiving the first notification last autumn (1982). I went to the Office of Clinical Investigation and asked to have my project placed on an inactive status. There were several reasons for this action.

For a good portion of last year (June through November 1982) I was either on TDY orders or working at a clinic away from Walter Reed Army Medical Center. Furthermore, to date I have not had any subjects involved in my study. Part of the reason for this is that I had not clearly defined how I intended to randomize my study. In addition, there was some question as to whether other surgeons would comply with the protocol as outlined.

when I approached the Clinical Investigation Department last autumn it was my understanding that by placing my study, which clinically had not started, on an inactive list I would not have to file an annual report.

I applogize for my misunderstanding and any inconvenience this may have caused. I do intend to reactivate my study with the necessary changes this spring via the proper channels as outlined by the Department of Clinical Investigation.

Thank you.

Charles S. Tressler MD, CPT MC

DATE: 15 NOV 82 HOSK UNIT No.: 2314	STATUS: INTERIM FINAL X
STARTING DATE: JULY 1981 DATE OF	COMPLETION: N/A
Key Horas:	
Time of Project: Comparison of External Me Entropic, and Ectropic Li	-
PRINCIPAL INVESTIGATOR(s): Kevin G. Maguire, CH	PT, MC
ASSOCIATE INVESTIGATOR(S): N/A	· · · · · · · · · · · · · · · · · · ·
FACILITY: WRAYE DEPT/Svc: OPHT	THALMOLOGY
ACCUMULATIVE PEDCASE COST: ACCUMULATIVE CONTRACT 0	COST: ACCUMULATIVE SUPPLY COST:
FY-83 I'EDCASE: CONTRACT COST: Supply Cost:	DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT N/A
STUDY OBJECTIVE:	
TECHNICAL APPROACH:	
PROGRESS DURING FY-82:	
MUMBER OF SUBJECTS STUDIED:	· · · · · · · · · · · · · · · · · · ·
FY-82: TOTAL (TO DATE):	BEFORE COMPLETION OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPAT	ING IN PROJECT(IF NONE SO STATE):
CONCLUSIONS: Protocol terminated, in assigned to WRAMC.	nvestigator is no longer
PUBLICATIONS OF ABSTRACTS FY-82:	

For use of this form, see AR 340-15, the prepenent agency is TAGCEN.

REFERENCE ON OFFICE SYMBOL SUBJECT A
HSHL-SI Program

WWECT Annual Progress Report: FY 82, Clinical Investigation Program, Work Unit #2315, "Results in Strabismus Employing the WRAMC Modification of Adjustable Suture Technique of Doular Rectus Muscle Recession."

Deular Rectus Muscle Recession."

FROM DATE

C, Dep Clin Invest, WRAMC

Ophthal Svc, WRAMC

14 January, 1983 Dr. Katz:fkm 6/1964

- 1. Reference the above Work Unit, the clinical investigation project was completed 30 June, 1982. The results were reported at the Biennial Walter Reed Alumni Meeting and Post-Graduate Ophthalmology Course. The results are being prepared in paper form for publication.
- 2. The manuscript when completed will be forwarded to the Clinical Investigation Department for approval prior to sending for publication.
- 3. The accumulative MEDCASE, contract, supply, cost and items J,K,L,M,N,0,P, & Q are not applicable.

Norman N.K. Katz, MD

COL, MC US ARMY

Ophthalmology Svc, Dept Surg, WRAMC

DATE: 26 JAN 83 VOR UNIT No.: 2400	Status: Interim X Firm
STARTING DATE: October 1980 DATE OF C	Ist Phase by JAN 84
Key Nords:	
TITLE OF PROJECT:	
Clinical and Biomechanical Investigation of	Knee Ligament Laxity
PRINCIPAL INVESTIGATOR(S): Dr. Myron D. Tremaine	
ASSOCIATE INVESTIGATOR(S): Dr. Youngil Youm	
FACILITY: KRAYC DEPT/Svc: Dept of	of Surgery, Orthopaedic Service
Accumulative PEDCASE Cost: Accumulative Commact Concess.	ST: ACCURATIVE SUPPLY COST: TEASEL SUPPLIES : \$200 EST \$600
FY-83 FEDCASE: CONTRACT COST: SUPPLY COST:	ATE OF COMMITTEE APPROVAL OF 2 5 1983
STUDY OBJECTIVE: Complete knee stress machine,	complete psychological testing
profile, complete computerization of Cybex	Isokinetic machine
TECHNECAL APPROACH:	
No modifications to original protocol	
PROGRESS BURING FY-82: No subjects studied, but	knee stress machine and computerization
of Cybex machine almost completed. Ready for Psychological testing started. Not complete	
Muyser of Subjects Studied:	
FY-82: TOTAL (TO DATE): Approx 50	BEFORE COMPLETION OF STUDY:
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING	IN PROJECT(IF HOME SO STATE):
No serious side effects	<u> </u>
CONCLUSIONS:	
Pur ICATIONS OF ARSTRACTS FY-87.	

One abstract submitted to Engineering Journal describing knee stress machine. Anticipate a patent, and probably another abstract concerning Cybex Computerization

DATE: 30 Sep 82 WORK UNIT NO.: 2517 STATUS: INTERIM FINAL X DATE OF COMPLETION: STARTING DATE: August 1977 September 1982 KEY WORDS: aural rehabilitation, rehabilitation, lipreading, auditoryvisual integration TITLE OF PROJECT: Evaluation of a Specialized Technique for Training Audio-Visual Integration PRINCIPAL INVESTIGATOR(S): Allen A. Montgomery ASSOCIATE INVESTIGATOR(S): Brian E. Walden, Daniel M. Schwartz, Robert A. Prosek, Earl Wilkinson FACILITY: WRAMC DEPT/SVC: Dept. of Surgery/Otolaryngology Service ACCUMULATIVE MEDCASE ACCUMULATIVE CONTRACT ACCUMULATIVE SUPPLY COST: FEB 2 5 1983 COST: COST: FY-83 MEDCASE: CONTRACT COST: SUPPLY COST: DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT STUDY OBJECTIVE: This study is designed to evaluate the effectiveness of a

STUDY OBJECTIVE: This study is designed to evaluate the effectiveness of a newly-developed training procedure for improving patients' ability to use the audible and visible aspects of speech simultaneously [audio-visual integration (AVI)].

TECHNICAL APPROACH: Twenty-four hard-of-hearing patients were divided into control and experimental groups and tested before and after receiving either traditional rehabilitation or the AVI technique. The AVI training was done individually in 10 one-hour sessions by trained rehabilitationists. The before and after testing consisted of a 100-item sentence test presented audiovisually in noise, and the data were analyzed with parametric statistics (t-tests and ANACOVA). In addition, a group of 12 normally-hearing people were tested at a similar interval to assess the learning effects of the test.

PROGRESS DURING FY-82: The data were reanalyzed and the manuscript was revised to address the important issue of the effect of guessing on pre- and post-testing performance. This issue was raised by a recent study and reflects directly on our data. The issue has been resolved in our favor, and the study has been strengthened by the additional analysis.

Annual Progress Report (cont.) - Work Unit #2517

NUMBER OF SUBJECTS STUDIED: FY-82: 0 TOTAL (TO DATE): 24 BEFORE COMPLETION OF STUDY:	24
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT (IF NONE SO STATE): None.	
CONCLUSIONS: The technique appears to be a useful and efficient way to improve new hearing aid users' ability to use the visual (lipreading) component and the auditory component of speech simultaneously.	
PUBLICATIONS OR ABSTRACTS, FY-82: A manuscript is in preparation for submission to Ear and Hearing .	

DATE: 30 Sep 82	WORK UNIT NO .:	2523 STAT	TUS: INTERI	M FINAL X
STARTING DATE: Jun	ne 1978	DATE OF CO	MPLETION:	September 1982
KEY WORDS: hearing	g aids, quality ju	dgments, elec	troacoustic	
TITLE OF PROJECT:	The Relationship Perceived Sound C			Parameters and
PRINCIPAL INVESTIGA	ATOR(S): Daniel M	1. Schwartz		
ASSOCIATE INVESTIGA		Montgomery, David H. Layl		lden, Robert A.
FACILITY: WRAMC	DEPT/SVC:	Dept. of Surg	gery/Otolary	ngology Service
ACCUMULATIVE MEDCAS COST: \$18,650	SE ACCUMULA COST:	ATIVE CONTRACT		CUMULATIVE SUPPLY
FY-83 MEDCASE: CO	ONTRACT COST: SUE	PPLY COST:		MMITTEE APPROVAL PROGRESS REPORT 25 1983
STUDY OBJECTIVE: dimensions and the sound quality of he	physical characte	ristics of he		
TECHNICAL APPROACH an interpretive re- processed through comparison format. equipped with Zwis- For the playbe quency hearing loss two types of responsased on the quali- ratings were made represented very so of identifying the	ading from "The Adeach of 20 commerce. The recording production of the recording product of the hearing on a 7-point equalimitar and 7 dissipation."	iventure of To cially available cocedure was a mulators. al hearers, 10 at loss were of similarity and aid processed appearing in	om Sawyer" woole hearing accomplished accomp	as hearing aid aids in a paired lusing KEMAR with high fre- tted to furnish of preference similarity as, where latents consisted
PROGRESS DURING FY-	-82: None.			

Annual Progress Report (cont.) - Work Unit #2523

 OF SUBJEC		:	20 B	EFORE	COMPLETIC	N C	OF STUDY:	
/UNEXPECT	EFFECTS	IN	SUBJECTS	PARTI	CIPATING	IN	PROJECT	(IF

CONCLUSIONS: The finding that low-frequency cutoff dominates listener judgments of hearing aid sound quality is in direct contrast to the amplification needs of hearing impaired patients. That is, an extensive body of research literature suggests that amplification of low frequeny speech sounds and noise may create an upward spread of masking and thus degrade the intelligibility of speech. Hence, the data of the present study reveals that the electroacoustic characteristic that results in the best sound quality, i.e., low low-cutoff frequency, may not be the one that results in improved speech understanding with a hearing aid.

PUBLICATIONS OR ABSTRACTS, FY-82: A manuscript is being prepared for submission to the <u>Journal of Speech and Hearing Research</u>.

NOTE: The Principal Investigator on this protocol has resigned his position effective 1 October 1982.

WORK UNIT NO.: 2525 STATUS: INTERIM X FINAL DATE: 30 Sep 82 DATE OF COMPLETION: February 1983 STARTING DATE: August 1978 KEY WORDS: lipreading, synthetic speech, computer graphics, aural rehabilitation TITLE OF PROJECT: Generation and Evaluation of Synthetic Facial Images for Studying and Training Lipreading PRINCIPAL INVESTIGATOR(S): Allen A. Montgomery ASSOCIATE INVESTIGATOR(S): Brian E. Walden, Robert A. Prosek, Daniel M. Schwartz, Kweon I. Stanbaugh DEPT/SVC: Dept. of Surgery/Otolaryngology Service FACILITY: WRAMC ACCUMULATIVE MEDCASE ACCUMULATIVE CONTRACT ACCUMULATIVE SUPPLY COST: \$7,595.00 COST: COST: \$692.60 FY-83 MEDCASE: CONTRACT COST: SUPPLY COST: DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983

STUDY OBJECTIVE: This study is designed to evaluate the feasibility of simulating on a computer graphics system, the information-bearing elements of the talker's mouth and face during speech, for the purpose of studying lipreading in hard-of-hearing patients.

TECHNICAL APPROACH: The final phase of this project involves the incorporation of phoneme-timing information into the model, the development of realistic standards for forward and backward coarticulation, the software revision to allow direct phoneme-to-image translation, and the evaluation of the system with hearing impaired subjects.

PROGRESS DURING FY-82: The timing information has been gathered from several sources and is available for incorporation into the computer-based model. Standards for the exact amount of coarticulation that is needed to produce natural-appearing visual images have been developed, but seem to be unnecessarily complex and dependent on the specific consonants and vowels involved. The software has been revised to permit approximately a 10:1 reduction of the time required to convert phoneme information to animated images. However, when the timing subroutine is incorporated in final form, we anticipate another significant reduction in the conversion time. Evaluation of the system is scheduled to begin in mid-October.

Annual Progress Report (cont.) - Work Unit #2525

NUMBER OF SUBJECTS STUDIED: FY-82: 0 TOTAL (TO DATE): 20 BEFORE COMPLETION OF STUDY: 30
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT (IF NONE SO STATE): None.
CONCLUSIONS: Technical refinements and software modifications dominated the research effort during FY-82. The animated images that the system produces now are, in general, quite realistic and a successful evaluation is anticipated.
PUBLICATIONS OR ABSTRACTS, FY-82:
Montgomery, A. A., and SooHoo, G. ANIMAT: A set of programs to generate, edit, and display sequences of vector-based images. Behavior Research Methods & Instrumentation, 14(1), 39-40, 1982.

WORK UNIT NO.: 2526 INTERIM X FINAL DATE: 30 Sep 82 STATUS: STARTING DATE: January 1979 DATE OF COMPLETION: September 1983 KEY WORDS: self-assessment, inventory, hearing impaired, communication TITLE OF PROJECT: Development of a Communication Self-Assessment Inventory of the Hearing Impaired Soldier PRINCIPAL INVESTIGATOR(S): Marily E. Demorest, Sue A. Erdman ASSOCIATE INVESTIGATOR(S): Roy K. Sedge FACILITY: WRAMC DEPT/SVC: Dept. of Surgery/Otolaryngology Service ACCUMULATIVE MEDCASE ACCUMULATIVE CONTRACT ACCUMULATIVE SUPPLY COST: COST: COST: \$1621.60 FY-83 MEDCASE: CONTRACT COST: SUPPLY COST: DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 25 1983 \$6000.00

STUDY OBJECTIVE: The objective of this project is to develop a communication self-assessment inventory to be used in the inpatient Aural Rehabilitation Program of the Army Audiology and Speech Center, WRAMC. The specific purposes of this inventory are:

- a. To assess progress in environmental control, and in emotional, social, familial, and vocational adjustment to the handicap as a result of the Aural Rehabilitation Program (i.e., a quantitative index of improvement provided by pre- and post-program scores).
- b. To establish a baseline for planning a patient's environmental control training and adjustment counseling in the Aural Rehabilitation Program.
- c. To provide prognostic indicators of short-term success in communication (pre-program administration).
- d. To provide prognostic indicators of long-term success in communication after returning to duty station (post-program administration).

TECHNICAL APPROACH: Having determined during FY-80 that the Hearing Performance Inventory (T.C. Giolas et al., JSHD, 1979) would not fulfill the Army's needs for a communication inventory (see FY-80 APR), we undertook to develop our own inventory. A large pool of items was developed and administered to a large number of patients. Responses to the inventory were subjected to statistical analysis. A revised version of 155 items is currently being tested as a final phase of inventory development.

PROGRESS DURING FY-82: The original form consisting of 215 items was modified following statistical analyses. The revised form is comprised of 155 items. On the basis of clinical observations and factor analyses, the scales and subscales were also revised to provide more specific information to the clinician. The scales include revisions of Communication Performance, Communication Environment, Behavioral Adjustment, and Personal Adjustment. The Communication Information scale was deleted. A new scale was included to address Communication Strategies. (Additional information regarding the revised scales and subscales can be obtained from the Audiology Section upon request.)

The attempt to automate the testing process utilizing the laboratory computer system was unsuccessful. At this time efforts are being made to evaluate an optical scanner system for processing patient responses.

NUMBER OF SUBJECTS STUDIED:	
FY-82: 300 TOTAL (TO DATE): 407 BEFORE COMPLETION OF STUDY	: 700
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT NONE SO STATE): None.	(IF
CONCLUSIONS: Not applicable at this time.	,,,
PUBLICATIONS OR ABSTRACTS, FY-82: Not applicable at the present time	•

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-SES

Clarification of Annual Progress Report for Work Unit # 2526

FROM

Sue A. Erdman, M.A.

DATE 14 December 1982

CMT 1

TO

Dr. Hanson

Dr. Boehm, Chief DCI

- 1. The following information/explanation is furnished at your request for clarification of budget changes in Work Unit #2526.
- 2. It has been proposed that Dr. Marilyn Demorest (formerly Wang) return to WRAMC on a full time basis for work on this project during the summer of 1983. Final statistical analysis and publication of the Communication Profile for the Hearing Impaired in test manual form (in compliance with APA guidelines) can be accomplished within this time frame if she extends her work here to a full-time basis for a two month period. She will have worked on this project for nearly two years as a Red Cross Volunteer following her initial year here (1980) on temporary hire. Data analyses during the summer of 1983 will involve results from nearly 1000 subjects, two revised forms of the questionnaire in addition to audiometric data for the relevant subjects.
- 3. Our current time and staff constraints would preclude accomplishing these goals within the desired time frame. Inability to fund the remaining work on this project could necessitate relinquishing the project to another facility or significant delays in the completion of the study, publication of the results and the test materials in manuscript and/or manual form.

Sue Ann Erdman, M.A.

Audiologist AA&SC, WRAMC

Principal Investigator

DATE: 30 Sep 82	WORK UNIT NO.:	2529 STATE	S: INTERIM	FINAL X
STARTING DATE: Apri	1 1981	DATE OF COM	IPLETION: 30 Sep	82
KEY WORDS: auditory	brainstem respo	nse, high free	uency hearing lo	088
TITLE OF PROJECT: E	ffect of High Fr he Latency of th			Loss on
PRINCIPAL INVESTIGATO	DR(S): Daniel M	. Schwartz		
ASSOCIATE INVESTIGATO	OR(S): Don B. B Henderso	•	K. Sedge, Robert	t L.
FACILITY: WRAMC	DEPT/SVC:	Dept. of Surge	ry/Otolaryngolo	gy Service
ACCUMULATIVE MEDCASE COST:	ACCUMULA COST:	TIVE CONTRACT	ACCUMULA'	TIVE SUPPLY
FY-83 MEDCASE: CON	TRACT COST: SUF	PLY COST:	DATE OF COMMITTED OF ANNUAL PROGREE FEB 25	ESS REPORT
STUDY OBJECTIVE: To the role of mathemat:				loss and
TECHNICAL APPROACH: with disc electrodes recorded to alternate dB NHL.	attached to the	vertex and ea	rlobes. Respons	ses were
PROGRESS DURING FY-82	2: 48 sensorine	ural hearing l	oss subjects hav	re been
NUMBER OF SUBJECTS ST FY-82: 8 TOTAL		8 BEFORE	COMPLETION OF ST	JDY: 48
SERIOUS/UNEXPECTED STATE): None		UBJECTS PARTIC	CIPATING IN PROJ	CT (IF
CONCLUSIONS: Click passence of wave I was and alternating click the cases at 65 dB N	found to incre	ase considerat	ly when using co we I was absent	in 56% of

absent least often (16%) for rarefaction clicks at 85 dB NHL. High frequency hearing loss at 6000 Hz tended to correlate best with wave V latency delay such that a delay of 0.1 msec was shown to occur with every 10 dB of hearing loss. Analysis of the individual scatter of data, however, showed the error that would occur if such a correction factor was used. Not only did statistical analysis reveal that only 17% of the variance was accounted for solely on the basis of hearing loss, but scatter plots of the data showed that over or underestimates of latency delay will occur if one uses a correction factor.

What proved valuable, however, was to use a single index of seven milliseconds for wave V latency and 4.6 msec for the I-V inter-peak latency to demarcate between cochlear and VIIIth nerve tumor ears.

PUBLICATIONS OR ABSTRACTS, FY-82: Manuscript in preparation for submission to a scientific journal.

NOTE: The Principal Investigator on this protocol has resigned his position effective 1 October 1982.

WORK UNIT NO.: 2530 STATUS: INTERIM FINAL X DATE: 30 Sep 82 DATE OF COMPLETION: July 1982 STARTING DATE: May 1980 TITLE OF PROJECT: Test of the Assumptions Underlying the Comparative Hearing Aid Evaluation KEY WORDS: comparative hearing aid evaluation, hearing aids, validity, reliability PRINCIPAL INVESTIGATOR(S): Brian E. Walden ASSOCIATE INVESTIGATOR(S): Joanne M. Crowley, Daniel M. Schwartz, Dennis L. Williams, Michael H. Mayer DEPT/SVC: Dept. of Surgery/Otolaryngology Service FACILITY: WRAMC ACCUMULATIVE SUPPLY ACCUMULATIVE MEDCASE ACCUMULATIVE CONTRACT COST: COST: COST: FY-83 MEDCASE: CONTRACT COST: SUPPLY COST: DATE OF COMMITTEE APPROVAL OF ANNUAL PROGRESS REPORT FEB 2 5 1983

STUDY OBJECTIVE: The purpose of this research is to test the assumptions which underlie the comparative hearing aid evaluation (CHAE). Among the questions to be answered are: a) Do clinically and statistically significant performance differences exist among hearing aids preselected to be appropriate to the patient's hearing loss? b) Does the same instrument tend to be best for all patients? c) Are available test materials sufficiently reliable for use in hearing aid selection? d) Are the results of a CHAE stable over time? e) Do the results of a CHAE predict patient performance in the real world?

TECHNICAL APPROACH: Hearing-impaired subjects selected from the Aural Rehabilitation Program of the Army Audiology and Speech Center are administered a modified comparative hearing aid evaluation (CHAE) using three behind-the-ear instruments. The binomial model (at .95 confidence) is used to determine if significant differences exist among the aided monosyllabic word recognition in noise scores. In those cases where the interaid differences exceeded chance performance, two additional steps were taken. First, the patient was allowed to wear each of the three instruments for an extended period of time during the week following the initial CHAE. At the end of this trial use period, the patient indicated which aid was most acceptable and which was least acceptable. Second, following the trial use period, the CHAE was repeated.

PROGRESS DURING FY-82: Data acquisition was completed on a total of 45 hearing impaired subjects. Data reduction and statistical analysis were completed. A manuscript was prepared based on the findings of this investigation and was submitted for publication in the <u>Journal of Speech and Hearing Disorders</u>. Currently, it is under editorial review.

NUMBER FY-82:	OF SUBJECTS	STUDIED: TAL (TO DATE):	45	BEFORE	COMPLETION	OF	STUDY:	45
		 						

SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT (IF NONE SO STATE): There were no serious/unexpected side effects in subjects participating in this project.

CONCLUSIONS: When the hearing aids preselected for evaluation with a patient are relatively homogeneous electroacoustically, significant interaid performance differences on the hearing aid evaluation are not likely to occur very often. In contrast, when the aids are very different electroacoustically, significant interaid differences may occur frequently. In such cases, however, interactions between hearing aids and patient performance will be relatively rare. Further, unless there are fairly large electroacoustic differences among the instruments being evaluated, the test-retest reliability of standard monosyllabic word lists may not be adequate to detect typical interaid differences that occur in a comparative hearing aid evaluation. This appears to be the case even when 100-item test lists are used. The problem becomes greater, the shorter the test lists employed. The data also suggest that the performance hierarchy on the clinical evaluation can be expected to change for many patients as the new hearing aid user adjusts to amplification. Finally, the instrument which scores highest on the clinical evaluation is not necessarily the aid that would be judge most beneficial by the patient based on trial use in daily living unless relatively large interaid difference scores are obtained.

PUBLICATIONS OR ABSTRACTS, FY-82: A manuscript has been prepared and is currently under editorial review by the <u>Journal of Speech and Hearing</u> Disorders.

		1			
STARTING DATE: Sept	ember 1980	DATE OF C	OMPLETION:	October	1983
KEY WORDS: stuttering	ng, follow-up, di	sfluency, s	peech		
	sintenance of Spe tuttering Therapy		Following	an Inten	sive
PRINCIPAL INVESTIGATO	OR(S): Marcia D.	Bond-Liebe	rtz		
ASSOCIATE INVESTIGAT	W. Lohsen	lverwood, Pa a, Joyce Gur ai, Robert A	evich-Uven		
FACILITY: WRAMC	DEPT/SVC: D	ept. of Sur	gery/Otola	ryngology	Service
ACCUMULATIVE MEDCASE COST:		TIVE CONTRAC	- 1	CCUMULATIV	
FY-83 MEDCASE: CON	TRACT COST: SUPP	PLY COST:	OF ANNUA	COMMITTEE L PROGRESS ES 25 1999	REPORT
STUDY ORJECTIVE: To maintained by adult : Shaping Program duri	stutterers partic	ipating in	the Precis	ion Fluenc	су
TECHNICAL APPROACH: Precision Fluency Shithis study. Tape-resubject on five occasions and the subject on five occasions and the subject on five occasions and the subject of the subject o	aping Program at corded telephone sions: 1) prior completing the patherapy, 4) six giving permission speak for five y topic that interests.	Walter Reed monologues to the init rogram (fou months post on to record minutes abo	will be twill be obtation of rweeks af therapy, the monolut his spe	the subject tained from therapy () ter basel: and 5) nin ogue, the ech, or his	ts for om each baseline), lne), ne months subject is

WORK UNIT NO.: 2531

STATUS: INTERIM X

FINAL

DATE: 30 Sep 82

treatment.

session will be calculated for each subject for each post-therapy recording. Appropriate statistics will be applied to these data to determine if the fluency gains made by the program are retained when the subject finishes

Two general measures of fluency, percent syllables stuttered (%SS) and syllables per minute (SPM), will be obtained for each of the 150 monologues.

The improvement in each of these measurements relative to the baseline

PROGRESS DURING FY-82: During FY-82 progress has occurred in data acquisition and data reduction. Forty-seven patients have been recorded in the pre-therapy condition. Forty-three subjects have been recorded in the pre-therapy and immediate post-therapy condition. Of these, 28 have also been recorded at 3 months post-therapy; 23 at 6 months post-therapy; and 20 at 9 months post-therapy. Fifteen subjects have been recorded in all five conditions. Data reduction has begun in terms of transcribing each tape recorded session, counts of disfluencies, and measurement of monologue duration. To date, 50 taped sessions have been completed. This represents approximately one-third of the data reduction needed to begin data analysis.

Follow-up recordings have not been obtained from some subjects due to difficulty locating the subject and/or contacting the subject via telephone, particularly when the subject is in a duty location outside CONUS.

The number of subjects has been increased from 41 to 47 for the above reasons. Estimated completion date for data acquisition is November 1982.

NUMBER OF SUBJECTS STUDIED: FY-82:7	•
SERIOUS/UNEXPECTED SIDE EFFECTS IN SUBJECTS PARTICIPATING IN PROJECT (IF NONE SO STATE): None.	
CONCLUSIONS: Not applicable at the present time.	
PUBLICATIONS OR ABSTRACTS, FY-82: Not applicable at the present time.	_

DATE: 30 Sep 82 WORK UNIT NO.: 2533 STATUS: INTERIM X FINAL DATE OF COMPLETION: STARTING DATE: August 1980 August 1983 symmetric high-frequency hearing loss, monaural amplification, dichotic test Effect of Amplification on Dichotic Discrimination Test TITLE OF PROJECT: Results in Individuals with Primarily High Frequency Sensorineural Hearing Loss PRINCIPAL INVESTIGATOR(S): Rauna K. Surr, Daniel M. Schwartz ASSOCIATE INVESTIGATOR(S): H. Gustav Mueller, Susan Abernathy FACILITY: WRAMC DEPT/SVC: Dept. of Surgery/Otolaryngology Service ACCUMULATIVE CONTRACT ACCUMULATIVE SUPPLY ACCUMULATIVE MEDCASE COST: COST: COST: FY-83 MEDCASE: CONTRACT COST: DATE OF COMMITTEE APPROVAL SUPPLY COST: OF ANNUAL PROGRESS REPORT FEB 2 5 1983

STUDY OBJECTIVE: The purpose was to study the effect of monaural hearing aid use on dichotic listening task longitudinally in patients with predominantly high frequency sensorineural hearing loss.

TECHNICAL APPROACH: Twenty subjects with symmetrical high-frequency sensorineural hearing loss judged to be good hearing aid candidates were divided into two groups. One group was fitted with an aid for the right ear and the other for the left ear. Monotic and dichotic syllable discrimination tests were administered prior to the hearing aid use and then after one and six months of use. These data then would permit us to determine if monaural hearing aid use leads to an ear advantage (i.e., favoring one ear over the other for processing speech information) as has been suggested by Jacobsen (1979) on a flat hearing loss population.

PROGRESS DURING FY-82: All data have been collected and the analysis is in progress. A paper based on the preliminary analysis of these data was submitted and accepted for presentation at the Annual Convention of the American Speech-Language-Hearing Association, November, 1982, in Toronto, Canada.

		JECTS STU TOTAL	DIED: (TO DATE):		BEFORE	COMPLETIC	ON OF S	TUDY:
		ECTED SID	E EFFECTS	IN SUBJ	ECTS PART	CIPATING	IN PRO	JECT (IF
	SIONS: s date.		analysis	is not	complete (enough to	permit	conclusions
PUBLICA	ATIONS	OR ABSTRA	CTS, FY-82	: None				

